cogent BIOSCIENCES

Corporate Presentation

September 2026



Forward-Looking Statements and Risk Factors

This presentation and the accompanying oral commentary contain forward-looking statements that involve risks, uncertainties and assumptions. If the risks or uncertainties ever materialize or the assumptions prove incorrect, our results may differ materially from those expressed or implied by such forward looking statements. All statements other than statements of historical fact could be deemed forward-looking, including, but not limited to, any statements regarding: plans, strategies, and objectives of management for future operations, including our clinical development, regulatory and commercialization plans and timelines; any projections of financial information; historical results that may suggest trends for our business; expectation or belief regarding future events; potential markets, market opportunity or market size; technology developments; our clinical product pipeline, clinical and pre-clinical data or the implications thereof; enforceability of our intellectual property rights, competitive strengths or our position within the industry; anticipated patent exclusivity timelines; anticipated benefits of our collaborations or other strategic transactions; and any statements of assumptions underlying any of the items mentioned.

These statements are based on estimates and information available to us at the time of this presentation and are not guarantees of future performance. Actual results could differ materially from our current expectations as a result of many risks and uncertainties, including but not limited to, risks associated with: the potential impacts of raising additional capital, including dilution to our existing stockholders, restrictions on our operations or requirements that we relinquish rights to our technologies or product candidates; the success, cost, and timing of our product development activities and clinical trials; the timing of our planned regulatory submissions to the FDA for our product candidate bezuclastinib and feedback from the FDA as to our plans; our ability to obtain and maintain regulatory approval for our bezuclastinib product candidate and any other product candidates we may develop, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate; the potential for our identified research priorities to advance toward clinical development; the ability to license additional intellectual property relating to our product candidates from third parties and to comply with our existing license agreements and collaboration agreements; the ability and willingness of our third-party research institution collaborators to continue research and development activities relating to our product candidates; our ability to commercialize our products in light of the intellectual property rights of others; our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates; the scalability and commercial viability of our manufacturing methods and processes; the commercialization of our product candidates, if approved; our plans to research, develop, and commercialize our product candidates; our ability to attract collaborators with development, regulatory, and commercialization expertise; our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates; business interruptions resulting from public health crises, which could cause a disruption of the development of our product candidates and adversely impact our business; and the fact that interim clinical data may not be indicative of future results, among others. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to our business in general, see our periodic filings filed from time to time with the Securities and Exchange Commission. Unless as required by law, we assume no obligation and do not intend to update these forward-looking statements or to conform these statements to actual results or to changes in our expectations.

All of Cogent Biosciences, Inc.’s (“Cogent”) product candidates are investigational product candidates and their safety and efficacy have not yet been established. Cogent has not obtained marketing approval for any product, and there is no certainty that any marketing approvals will be obtained or as to the timelines on which they will be obtained.

Three Positive Pivotal Trials Position Bezuclastinib for Three Pending Approvals Across All KIT-mutant Driven Indications with Potential for Best-in-Class Efficacy

Peak GIST

Phase 3 trial in 2nd-line Gastrointestinal Stromal Tumors: sunitinib +/- bezuclastinib 600 mg

Positive Results Announced Nov 2025, BTD[1] Granted; NDA Accepted under RTOR[2], Assigned Nov 30, 2026 PDUFA

$4 billion+ Global Market Opportunity;

First positive 2nd-line GIST trial in over 20 years, 50% reduction in risk of progression or death, 16.5 month mPFS

Summit NONADVANCED SM

Pivotal trial in NonAdvanced Systemic Mastocytosis: bezuclastinib 100 mg vs. placebo

Positive Results Announced July 2025, NDA Accepted, Assigned Dec 30, 2026 PDUFA

$3.5 billion+ Global Market Opportunity;

Best-in-class symptomatic improvement and pathobiology data demonstrate potential for complete remission in patients

Apex ADVANCED SM

Pivotal trial in Advanced Systemic Mastocytosis: bezuclastinib 150 mg

Positive Results Announced Dec 2025; Assigned June 29, 2027 PDUFA

$500 million+ Global Market Opportunity;

Clearly differentiated safety/tolerability results provide clear path to market leadership

Total Global Market Opportunity exceeds $8 billion with limited competition;
IP protection anticipated through 2046 based on strength of COM + PTE and pending patent applications

[1]BTD: Breakthrough Therapy Designation, [2]RTOR: Real-time Oncology Review

cogent BIOSCIENCES

Cogent Biosciences Poised for Transformative 2026

Three Pivotal Trial Wins Position Bezuclastinib as Best-in-Class KIT inhibitor

PEAK: First ever positive trial in GIST patients using active comparator

SUMMIT: Demonstrated reduction in mast cell burden leads to substantial symptom improvements

APEX: Selective, non-CNS penetrant KIT inhibitor spares toxicities associated with current SOC

Prepare to Launch Bezuclastinib in 2026

2026

- Onboarded highly experienced US commercial team to prepare for anticipated 2H26 launch
- GIST PDUFA 11/30/26; NonAdvSM PDUFA 12/30/26; AdvSM 6/29/27 PDUFA

Strong Balance Sheet & Cash Runway

- $866 million pro forma 2Q26 cash balance; runway expected into late 2028

Creating Next-Gen, Best-in-Class Pipeline

- Focused on two franchises: Oncology & Hematology
- Pan-KRAS and JAK2 V617F inhibitors on track for IND 2026

Leadership with Deep Scientific Expertise in Precision Medicine



Andrew Robbins
President &
Chief Executive Officer



Jessica Sachs, MD
Chief Medical Officer



Cole Pinnow
Chief Commercial Officer



John Robinson, PhD
Chief Scientific Officer



Evan Kearns, JD
Chief Legal Officer



John Green
Chief Financial Officer



Erin Schellhammer
Chief People Officer



Brad Barnett
Chief Technology Officer

Building Robust Pipeline Across Two Franchises

	PROGRAM	TARGET	PATIENT POPULATION	PRE-CLINICAL	EARLY CLINICAL	LATE CLINICAL
HEMATOLOGY	Bezuclastinib	KIT D816V	Nonadvanced Systemic Mastocytosis (NonAdvSM)	December 30, 2026 PDUFA		
	Bezuclastinib	KIT D816V	Advanced Systemic Mastocytosis (AdvSM)	June 29, 2027 PDUFA		
	CGT1145	JAK2 V617F	Myeloproliferative Neoplasms	IND expected 2026		
	Undisclosed Targets					
ONCOLOGY	Bezuclastinib	KIT D816V	Gastrointestinal Stromal Tumors (GIST)	November 30, 2026 PDUFA		
	CGT4255	ErbB2	Breast Cancer, NSCLC	Phase 1 dose escalation ongoing		
	CGT6297	PI3Kα	Breast Cancer	Phase 1 dose escalation ongoing		
	CGT1815	pan-KRAS	Solid Tumors	IND expected 2026		
	Undisclosed Targets					

Bezuclastinib: Compelling Long-Term Exclusivity Expected Through 2046

2026 … 2029 2030 2031 2032 2033 2034 2035 2036 2037 2038 2039 2040 2041 2042 2043 2044 2045 2046

PATENT EXCLUSIVITY Orange Book listable patents

Compound patent
Original expiration date: **January 2034**

Patent term extension
Expected expiration date:
January 2039

Formulation patent (pending non-provisional application)
Expected expiration date: **December 2043**

Method of administration patent (pending provisional application)
Expected expiration date: **December 2046**

REGULATORY EXCLUSIVITY No ANDAs approved by FDA

New chemical entity (NCE) exclusivity
5 year: **2026-2031**

Orphan drug exclusivity (ODE)
7 year: **2026-2033**

BEZUCLASTINIB in Gastrointestinal Stromal Tumors



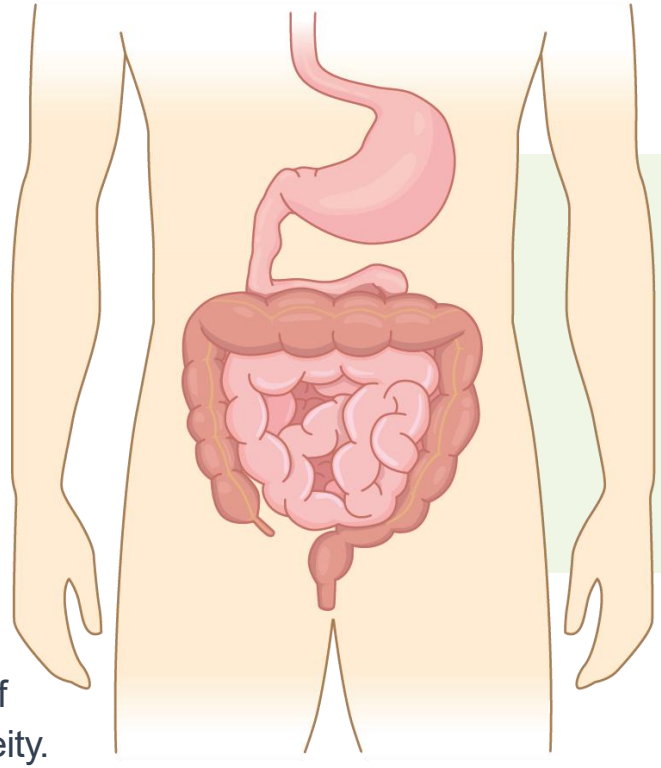
Significant Unmet Need Remains for Patients with Gastrointestinal Stromal Tumors (GIST)

Up to 12,000 GIST cases diagnosed annually in US and EU, over 80% of which express KIT mutations, typically exons 11 and 9.[1,2]

Tumors can start anywhere in the GI tract, but they occur most often in the **stomach (about 60%)** or the **small intestine (about 35%)**.[1]

While **imatinib provides disease control in the majority of patients** in the 1L setting, ~60% of patients with GIST develop resistance within 2 years, primarily due to mutations in exon 13/14 and/or exon 17/18.[1,2]

Additional FDA-approved sequential lines of therapy include sunitinib, regorafenib, and ripretinib; however, each is only effective against a subset of resistance mutations and disease progression results from clonal heterogeneity.



Symptoms[3]

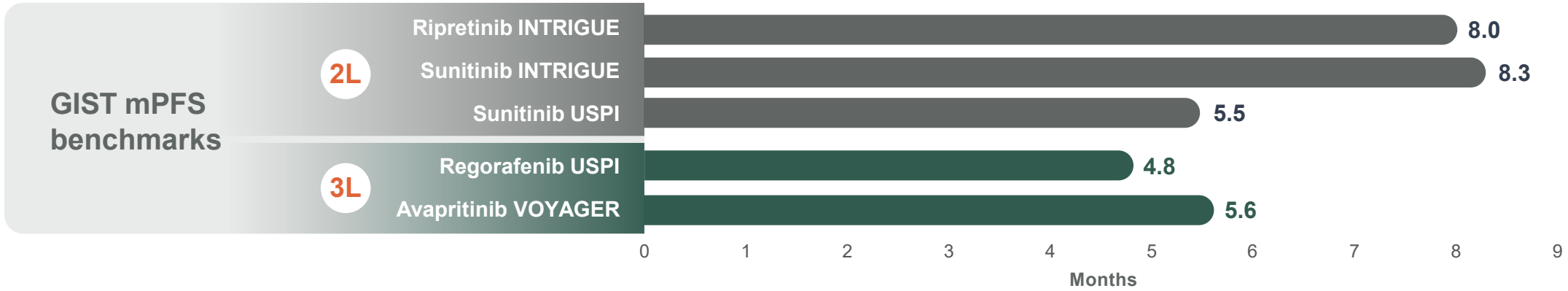
Diarrhea, Nausea, Vomiting, Abdominal pain, Bloating, Gastroesophageal reflux disease, GI bleeding, Loss of appetite,
Weight loss

1 Key statistics for gastrointestinal stromal tumors. American Cancer Society.
2 Gramza AW, Corless CL, Heinrich MC., 2009.
3 Signs and symptoms of gastrointestinal stromal tumors. American Cancer Society. L: Line of Therapy

Unmet Medical Need Remains for Patients with Imatinib-Resistant or Intolerant GIST



Modest historical performance of novel agents in imatinib-resistant setting emphasizes unmet need



ORR/PFS for all approved agents was obtained from labeled information from those agents

2026 ASCO® ANNUAL MEETING

Primary Results of the Phase 3 Peak Study of Bezuclastinib + Sunitinib vs Sunitinib Monotherapy in Advanced Gastrointestinal Stromal Tumors (GIST)

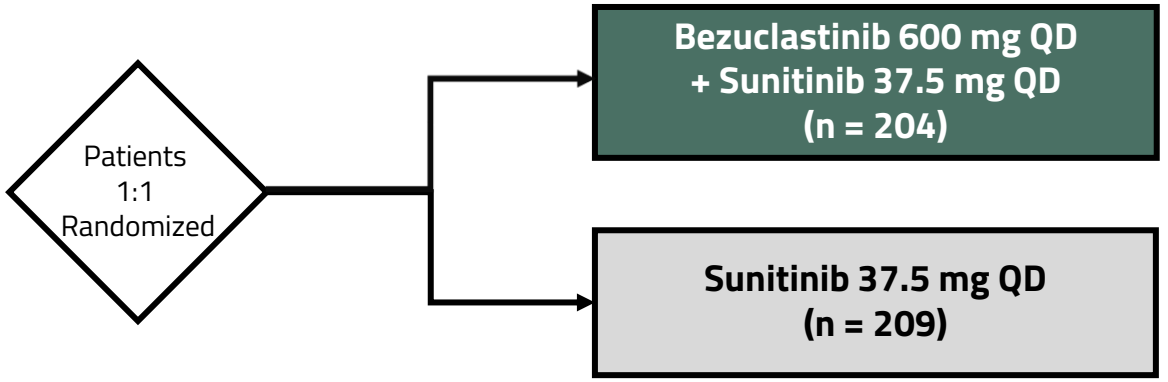
Andrew J. Wagner[1], Jonathan C. Trent[2], William D. Tap[3], Robin L. Jones[4], Sebastian Bauer[5], Margaret von Mehren[6], Michael C. Heinrich[7], Min-Hee Ryu[8], Breelyn A. Wilky[9], Albiruni R. Abdul Razak[10], Omar Farooq Khan[11], Felipe Pinto Negrete[12], Amanda Pilla[13], Zahabia Adenwala[13], Celeste LaHaie[13], Liangxing Zou[13], Lei Sun[13], Rachael Easton[13], Jessica Sachs[13], Neeta Somaiah[14]

1. Dana-Farber Cancer Institute, Boston, MA, USA; 2. University of Miami - Sylvester Comprehensive Cancer Center, Miami, FL, USA; 3. David H. Koch Center for Cancer Care at Memorial Sloan Kettering Cancer Center, New York, NY, USA; 4. The Royal Marsden Hospital and The Institute of Cancer Research, London, UK; 5. Universitätsklinikum Essen, Essen, Germany; 6. Fox Chase Cancer Center, Philadelphia, PA, USA; 7. Portland VA HCS and Oregon Health & Science University (OHSU), Portland, OR, USA; 8. Asan Medical Center, Seoul, South Korea; 9. University of Colorado Denver, Denver, CO, USA; 10. Princess Margaret Cancer Centre, Toronto, Canada; 11. Arthur J.E. Child Comprehensive Cancer Centre, Calgary, Alberta, Canada; 12. Centro de Oncología de Precisión, Universidad Mayor, Las Condes, Santiago, Chile; 13. Cogent Biosciences, Inc., Waltham, MA, USA; 14. MD Anderson Cancer Center, Houston, TX, USA.

Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

Peak Is a Global, Randomized, Open-label, Phase 3 Study

Evaluating the efficacy and safety of bezuclastinib + sunitinib vs sunitinib as 2L treatment (NCT05208047)



Crossover allowed following BICR-confirmed PD

Patient Eligibility
• Age ≥18 years • Histologically confirmed GIST with at least 1 measurable lesion per mRECIST v1.1 • Locally advanced, unresectable, or metastatic GIST • Documented disease progression on or intolerance to imatinib

Primary End Point	• PFS per BICR
Key Secondary End Points	• Objective response rate per BICR • Overall survival
Secondary End Points	• PFS per Investigator • Disease control rate • Time to response • Duration of response

Statistical assumptions: median PFS of 8 months for sunitinib and 12 months for bezuclastinib + sunitinib.

2L, second line therapy; BICR, blinded independent central review; GIST, gastrointestinal stromal tumor; mRECIST, modified response evaluation criteria in solid tumors; PD, progressive disease; PFS, progression-free survival; QD, once daily.

PRESENTED BY: Andrew J. Wagner, Dana-Farber Cancer Institute, Boston, MA, USA

Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

Peak Part 2 Population Is Representative of Patients With Imatinib-treated GIST

Patient Demographics	Bezuclastinib + Sunitinib	Sunitinib	Overall
Patients, n	204	209	413
Male, n (%)	131 (64.2)	133 (63.6)	264 (63.9)
Median age, years (range)	63 (32-83)	64 (30-88)	63 (30-88)
ECOG PS at baseline, n (%)			
0	140 (68.6)	132 (63.2)	272 (65.9)
1	61 (29.9)	74 (35.4)	135 (32.7)
2	3 (1.5)	3 (1.4)	6 (1.5)

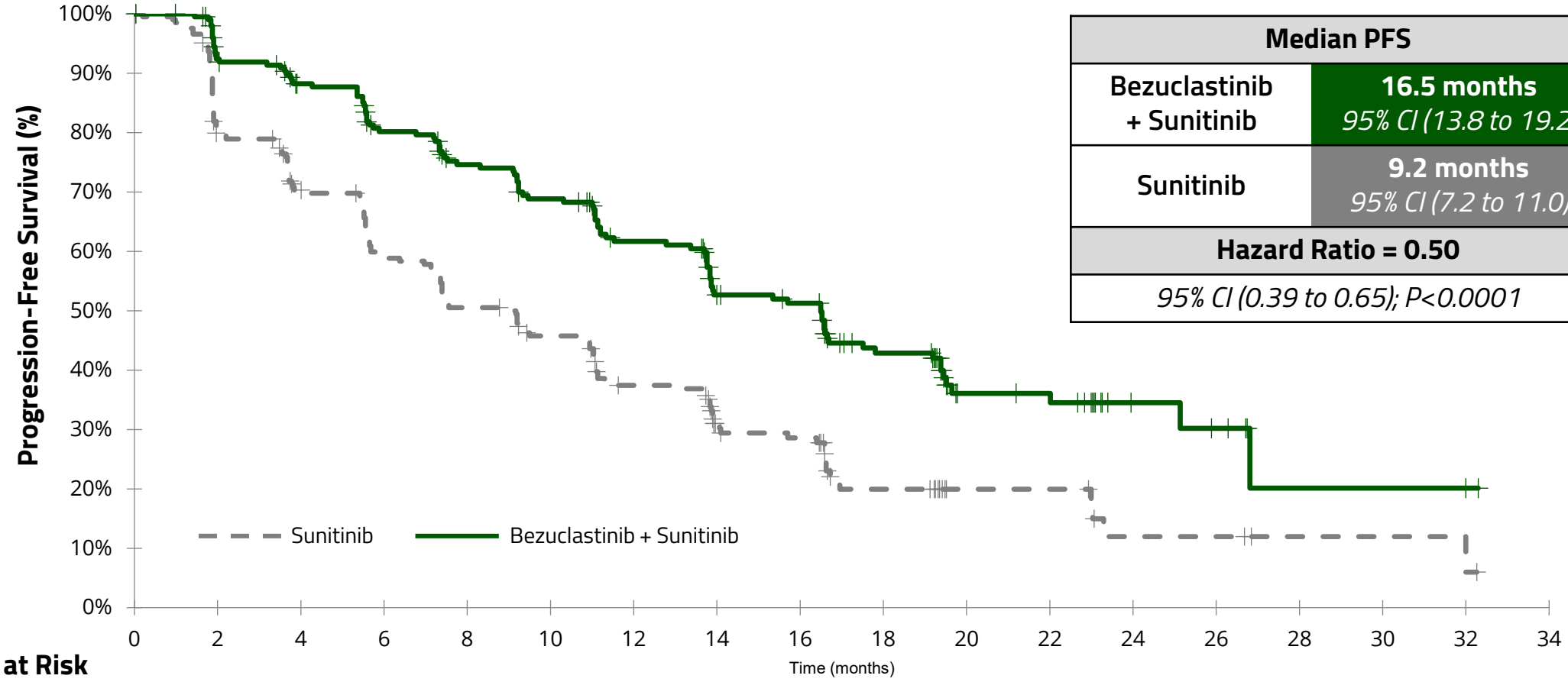
Region, n (%)	Bezuclastinib + Sunitinib	Sunitinib	Overall
North America	76 (37.3)	85 (40.7)	161 (39.0)
Europe	94 (46.1)	94 (45.0)	188 (45.5)
Latin America	20 (9.8)	11 (5.3)	31 (7.5)
Asia-Pacific	14 (6.9)	19 (9.1)	33 (8.0)

Baseline Characteristics	Bezuclastinib + Sunitinib	Sunitinib	Overall
***KIT* mutations per molecular pathology report, n (%)**			
Mutation detected			
Any exon 9	31 (15.2)	34 (16.3)	65 (15.7)
Any exon 11	151 (74.0)	161 (77.0)	312 (75.5)
Treatment history, n (%)			
Imatinib intolerance	6 (2.9)	8 (3.8)	14 (3.4)
Prior radiotherapy	14 (6.9)	8 (3.8)	22 (5.3)
Prior anticancer surgery	156 (76.5)	167 (79.9)	323 (78.2)

GIST, gastrointestinal stromal tumor; ECOG PS, Eastern Cooperative oncology Group Performance Status.

Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

Bezuclastinib + Sunitinib Extended PFS With 50% Reduction in Risk of Progression or Death



Median PFS	
Bezuclastinib + Sunitinib	**16.5 months** *95% CI (13.8 to 19.2)*
Sunitinib	**9.2 months** *95% CI (7.2 to 11.0)*
Hazard Ratio = 0.50	
95% CI (0.39 to 0.65); P<0.0001	

Patients at Risk

Bezuclastinib + Sunitinib	204	180	166	146	130	119	102	76	72	51	24	23	8	6	2	2	2	0
Sunitinib	209	161	137	113	97	85	64	39	35	19	9	9	4	4	2	2	2	0

CI, confidence interval; PFS, Progression-Free Survival

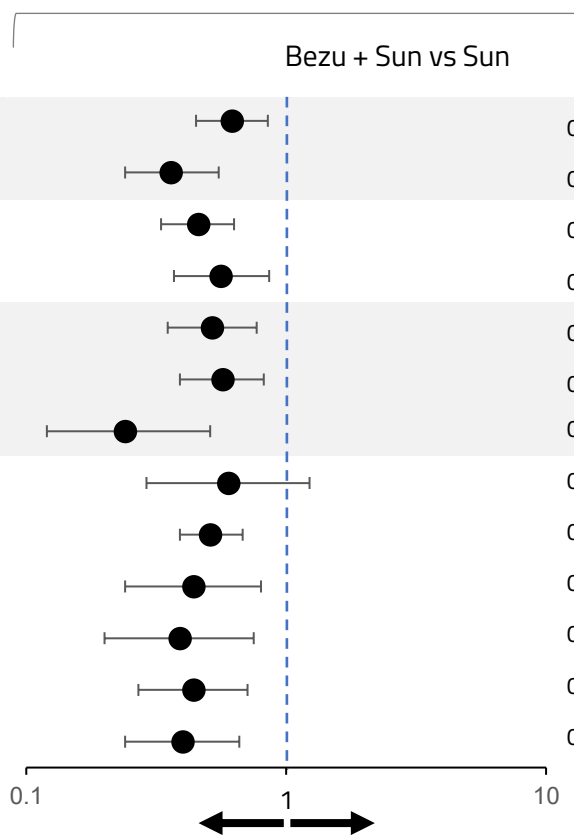
PRESENTED BY: Andrew J. Wagner, Dana-Farber Cancer Institute, Boston, MA, USA

Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

Data cut-off as of 30 September 2025

Bezuclastinib + Sunitinib Demonstrated PFS Benefit vs Sunitinib Monotherapy Across Subgroups and Baseline Mutation Profiles

Subgroup		Bezuclastinib + Sunitinib	Sunitinib	Hazard Ratio (95% CI)	Median, mos	
		Patients with primary outcomes, n/N (%)		Bezu + Sun vs Sun	Bezu + Sun	Sun
Age	<65	69/113 (61.1)	82/114 (71.9)	0.62 (0.45-0.85)	13.8	9.1
	≥65	37/91 (40.7)	66/95 (69.5)	0.36 (0.24-0.55)	19.4	9.2
Sex	Male	63/131 (48.1)	99/133 (74.4)	0.46 (0.33-0.63)	16.5	7.4
	Female	43/73 (58.9)	49/76 (64.5)	0.56 (0.37-0.86)	16.5	11.1
Race	White	45/80 (56.3)	58/85 (68.2)	0.52 (0.35-0.77)	13.9	9.2
	Not reported	49/96 (51.0)	68/95 (71.6)	0.57 (0.39-0.82)	13.9	9.1
	Other	12/28 (42.9)	22/29 (75.9)	0.24 (0.12-0.51)	19.5	7.6
KIT Mutations[a]	Any Exon 9	14/32 (43.8)	18/34 (52.9)	0.60 (0.29-1.23)	25.1	15.7
	Any Exon 11	84/153 (54.9)	119/163 (73.0)	0.51 (0.39-0.68)	15.3	7.4
	Any Exon 11 + 13/14	19/32 (59.4)	27/32 (84.4)	0.44 (0.24-0.80)	16.5	10.9
	Any Exon 11 + 17/18	15/27 (55.6)	22/27 (81.5)	0.39 (0.20-0.75)	13.8	2.0
	Any Exon 13/14	33/51 (64.7)	39/45 (86.7)	0.44 (0.27-0.71)	13.8	5.8
	Any Exon 17/18	32/51 (62.7)	34/43 (79.1)	0.40 (0.24-0.66)	13.8	3.5



[a] *KIT* mutation determination is based on pooled data from ctDNA samples collected at baseline and tumor-tissue sequencing collected at any time prior to study treatment.
Bezu, bezuclastinib; CI, confidence interval; ctDNA, circulating tumor DNA; mos, months; PFS, progression-free survival; Sun, sunitinib; y, year.

PRESENTED BY: Andrew J. Wagner, Dana-Farber Cancer Institute, Boston, MA, USA
Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

Bezuclastinib + Sunitinib Combination Significantly Improved ORR vs Sunitinib Monotherapy

Objective Response	Bezuclastinib + Sunitinib (n=204)	Sunitinib (n=209)
Objective response, % (95% CI)	**45.6** (38.6-52.7)	**25.8** (20.0-32.3)
P value[a]	**<0.0001**	
Best overall response, n (%)		
Complete response	**13** (6.4)	**4** (1.9)
Partial response	**80** (39.2)	**50** (23.9)
Stable disease	**91** (44.6)	**108** (51.7)
Progressive disease	**15** (7.4)	**41** (19.6)
Could not be evaluated	**5** (2.5)	**6** (2.9)

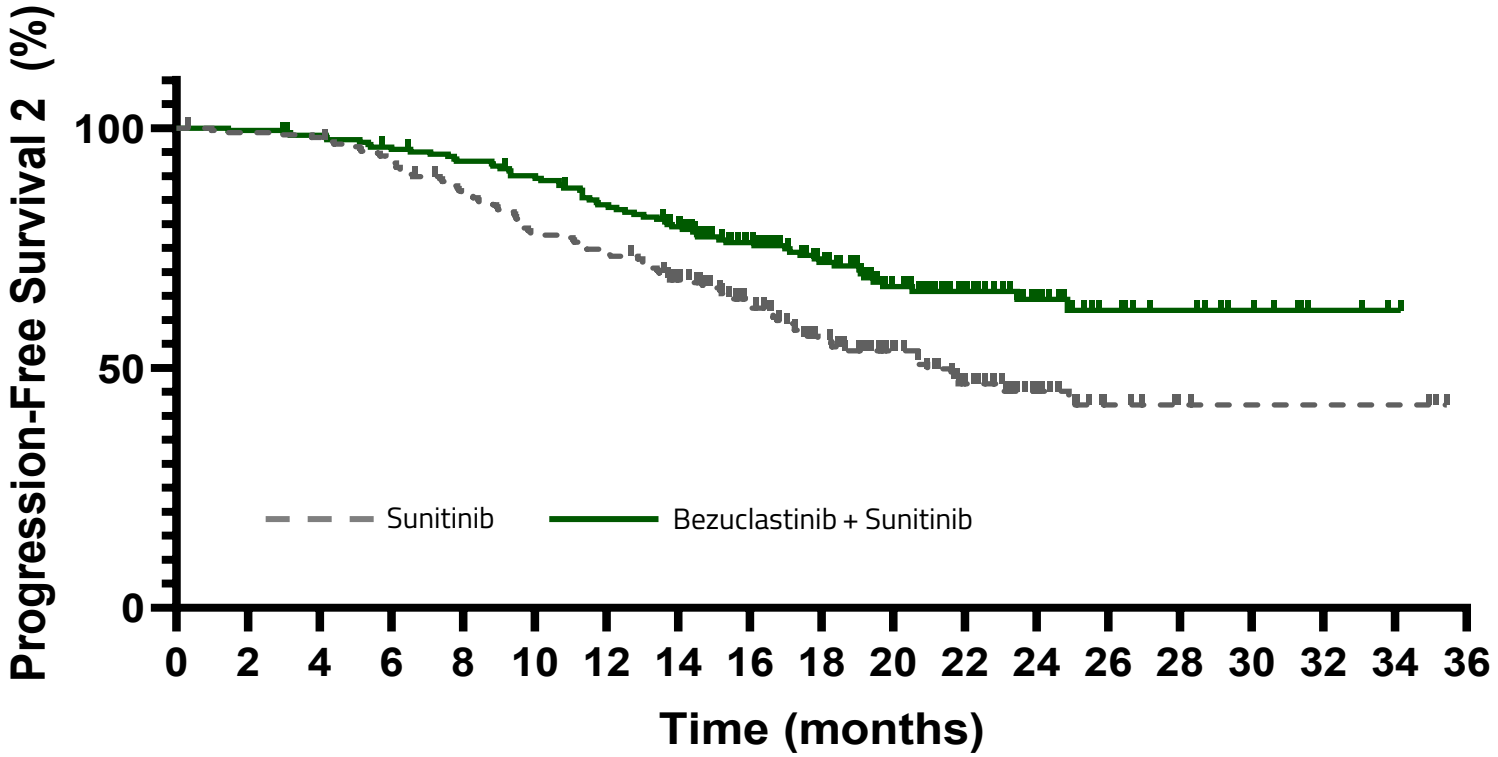
Additional End Points	Bezuclastinib + Sunitinib (n=204)	Sunitinib (n=209)
Disease control rate,%[b] (95% CI)	**86.8** (81.3-91.1)	**76.1** (69.7-81.7)
Median duration of response,[c] mos (95% CI)	**15.7** (12.2-NE)	**12.0** (7.6-14.9)
Median time to response,[c] mos (range)	**3.8** (1.6-26.6)	**3.7** (1.5-19.5)

- Based on analysis of best postbaseline change in global health status (EORTC-QLQ-C30[d]); **overall health and quality of life were not significantly different** between combination treatment and sunitinib monotherapy (improvement by LS mean, 9.1 vs 7.7, respectively).

[a]Two-sided. Based on Cochran-Mantel-Haenszel test stratified by the IRT stratification factors intolerance to imatinib (yes vs no) and *KIT* exon 9 mutation status (present vs absent). [b]Disease control rate defined as CR + PR + SD at 16 weeks. [c]Response defined as CR or PR. [d]LS mean is adjusted for baseline score. QoL data collection was limited to baseline through cycle 6 and at end of treatment.
CI, confidence interval; CR, complete response; EORTC-QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; LS, least squares; mos, months; NE, not evaluable; ORR, objective response rate; PR, partial response; QoL, quality of life; SD, stable disease.

PRESENTED BY: Andrew J. Wagner, Dana-Farber Cancer Institute, Boston, MA, USA
Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

PFS2 Results Support the Durability of Response to Combination vs Sunitinib Monotherapy



Patients at Risk

Bezuclastinib + Sunitinib	204	203	199	193	186	179	166	154	125	99	69	54	34	19	14	9	3	1	0
Sunitinib	209	206	204	193	177	160	152	133	101	77	60	41	22	9	4	3	3	3	0

Median PFS2	
Bezuclastinib + Sunitinib	Not yet reached
Sunitinib	21.0 months
Hazard Ratio = 0.57	

- PFS2 = time from randomization to progression on the next line of therapy or death
- Overall survival was immature with event rate of <20% as of data cut

For patients who crossed over from sunitinib monotherapy to combination, progression was based on BICR assessment during the crossover period. For all other patients, progression during subsequent anticancer therapy was based on investigator report.

BICR, blinded independent central review; PFS2, progression-free survival 2.

PRESENTED BY: Andrew J. Wagner, Dana-Farber Cancer Institute, Boston, MA, USA
Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

Bezuclastinib + Sunitinib Is Generally Well-Tolerated With a Favorable Safety Profile

	Bezuclastinib + Sunitinib (n=204)	Sunitinib (n=208)[a]
TEAEs, n (%)	204 (100)	207 (99.5)
TRAEs, n (%)	202 (99.0)	204 (98.1)
Gr3+ TRAEs, n (%)	146 (71.6)	109 (52.4)
Bezuclastinib related Gr3+	126 (61.8)	N/A
Sunitinib related Gr3+	141 (69.1)	109 (52.4)
SARs, n (%)	34 (16.7)	24 (11.5)
Bezuclastinib related SAEs	25 (12.3)	N/A
Sunitinib related SAEs	31 (15.2)	24 (11.5)
TRAEs leading to death, n (%)	0	1 (0.5)
Reductions of either drug due to TRAEs, n (%)	114 (55.9)	92 (44.2)
DC of study treatment due to TRAEs, n (%)	15 (7.4)	8 (3.8)

- The incidence of TEAEs and TRAEs was similar between treatment arms
- No TRAEs leading to death in patients on bezuclastinib + sunitinib combination
- Only TRAEs leading to discontinuation of either drug in >1 patient on the combination arm were neutropenia (2.9%), ALT/AST increased (1.5%), and diarrhea (1%)

Randomized period data.
[a]One patient randomized to sunitinib but never dosed.
ALT, alanine aminotransferase; AST, aspartate aminotransferase; DC, discontinuation; Gr, grade; N/A, not applicable; SAE, serious adverse event; SAR, serious adverse reaction; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event;

Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

All Grade TEAEs ≥ 20% Demonstrate Balance Between Arms

All grade TEAEs ≥ 20% in either treatment arm

	Bezuclastinib + Sunitinib (n=204)		Sunitinib (n=208)[a]	
Preferred term, n (%)	**All Grade**	**Grade 3+**	**All Grade**	**Grade 3+**
Diarrhea	159 (77.9)	16 (7.8)	138 (66.3)	15 (7.2)
ALT/AST increased[b]	115 (56.4)	22 (10.8)	35 (16.8)	3 (1.4)
Hypertension	106 (52.0)	60 (29.4)	108 (51.9)	57 (27.4)
Taste disorder[b]	97 (47.5)	0	52 (25.0)	0
Nausea	81 (39.7)	1 (0.5)	56 (26.9)	2 (1.0)
Hair color changes	79 (38.7)	0	37 (17.8)	0
Fatigue	72 (35.3)	9 (4.4)	70 (33.7)	5 (2.4)
Neutropenia[b]	71 (34.8)	31 (15.2)	70 (33.7)	32 (15.4)
PPE	59 (28.9)	6 (2.9)	95 (45.7)	5 (2.4)
Vomiting	56 (27.5)	2 (1.0)	45 (21.6)	4 (1.9)
Decreased appetite	55 (27.0)	6 (2.9)	46 (22.1)	0
Anemia	54 (26.5)	19 (9.3)	42 (20.2)	10 (4.8)
Abdominal pain	51 (25.0)	6 (2.9)	52 (25.0)	4 (1.9)
Stomatitis	46 (22.5)	6 (2.9)	68 (32.7)	10 (4.8)
GERD	45 (22.1)	0	30 (14.4)	0
Dyspepsia	43 (21.1)	5 (2.5)	29 (13.9)	0
Thrombocytopenia[b]	39 (19.1)	2 (1.0)	55 (26.4)	9 (4.3)

- TEAEs reported at a higher frequency (>15%) in combination arm: ALT/AST increased, taste disorder, and hair color changes
- TEAEs reported less frequently in combination arm: PPE, stomatitis and thrombocytopenia
- The safety profile of bezuclastinib combination is generally consistent with the known safety profile of sunitinib alone, and no new risks were identified with the combination

Randomized period data;

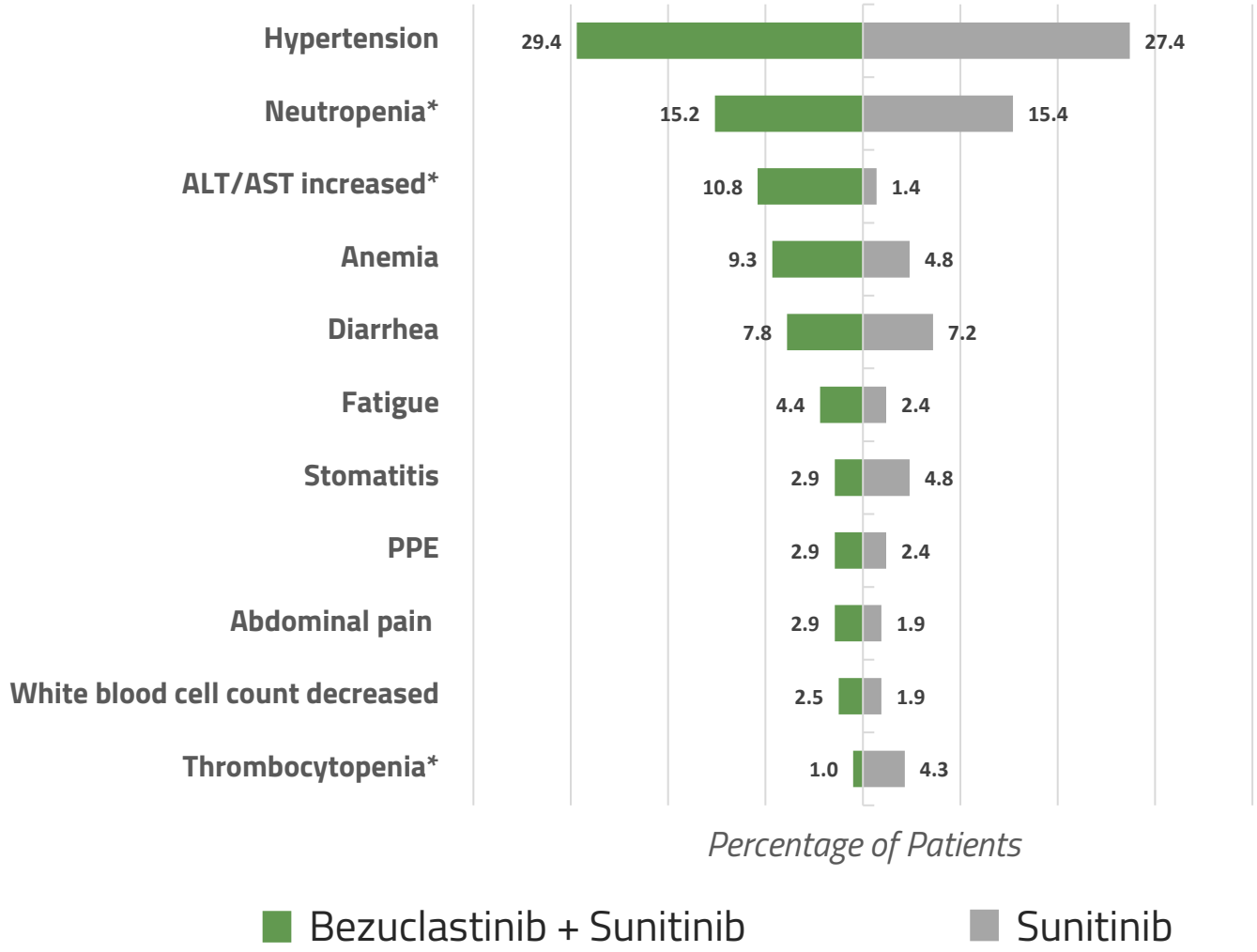
[a]One patient randomized to sunitinib but never dosed. [b]Pooled terms.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; GERD, gastroesophageal reflux disease; PPE, palmar-plantar erythrodysesthesia; TEAE, treatment-emergent adverse event.

PRESENTED BY: Andrew J. Wagner, Dana-Farber Cancer Institute, Boston, MA, USA

Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

Incidence of Grade 3+ TEAEs (≥2%) Balanced Across Arms



- Majority of the Gr 3+ TEAEs were reported at a similar rate between combination and monotherapy arms; ALT/AST increase and anemia reported at higher incidence in the combination arm
- No increase in frequency of severe events observed in combination arm for some key risks seen with sunitinib (hypertension, neutropenia, diarrhea, and PPE)
- ALT/AST elevations led to bezuclastinib dose reductions in 12.7% and only 1.5% of patients discontinued. All Grade 3 ALT/AST events resolved, and no Grade 4 elevations were reported.

*Pooled Terms

ALT, alanine aminotransferase; AST, aspartate aminotransferase; Gr, grade; PPE, Palmar-Plantar Erythrodysesthesia; TEAE, treatment-emergent adverse event.

Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

Conclusions

The Peak study represents the first time a combination of inhibitors targeting the same kinase in KIT-mutant GIST has delivered a significant efficacy benefit, balanced with a manageable safety profile.

Bezuclastinib + sunitinib demonstrated significantly superior efficacy

- Risk of progression or death was reduced by 50%
- 46% ORR is unprecedented in 2nd line GIST treatment
- Robust treatment effect consistent across subgroups and baseline mutation profiles

No new safety risks were identified with the combination of bezuclastinib + sunitinib

- Transaminase elevations were generally asymptomatic and reversible and did not result in more serious hepatic outcomes
- Lower rates of palmar-plantar erythrodysesthesia syndrome, stomatitis, and thrombocytopenia with the combination
- Overall health and quality of life were similar between treatment arms

Mutational heterogeneity of resistant GIST is more effectively treated with the combination of two kinase inhibitors, bezuclastinib + sunitinib

GIST, gastrointestinal stromal tumor; PFS, progression-free survival.

PRESENTED BY: Andrew J. Wagner, Dana-Farber Cancer Institute, Boston, MA, USA
Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

PEAK Results Dramatically Change 2nd-line GIST Commercial Potential Given Estimated Average Duration of Treatment

Large Population with Unmet Need



US + EU: 12,000 GIST patients diagnosed annually

~85% KIT driven

~60% imatinib resistant within 2 years



~6,000

2nd-line GIST patients annually

Approved KIT Inhibitors Monthly Price Benchmark*

QINLOCK® (ripretinib) 50 mg tablets

$47,932

AYVAKIT® avapritinib | tablets

$42,838

PEAK Results Show Dramatic Improvement in Duration of Treatment (DOT)

>21+ months

(est. mean duration treatment)

2nd-line GIST Total Available Market

$4 Billion+ Global

* Price listed 30-day supply U.S. WAC pricing

PEAK Results are Transformative and Expected to be Practice Changing

Bezuclastinib combination establishes first new benchmark for 2L GIST in 20 years

50% reduced risk of progression or death compared to current standard of care

16.5 months mPFS compared to 9.2 months for sunitinib alone (p<0.0001)

46% ORR compared to 26% for sunitinib alone (p<0.0001)

OS immature with event rate of **less than 20%** at time of PFS analysis



Generally well tolerated with **no unique risks observed** when compared to the known safety profile of sunitinib

Estimated **21 months+ mean treatment duration** for bezuclastinib combination patients based on projection for patients remaining on combination therapy

Active **Expanded Access Program allowing immediate availability** of the bezuclastinib combination for 2L patients with GIST

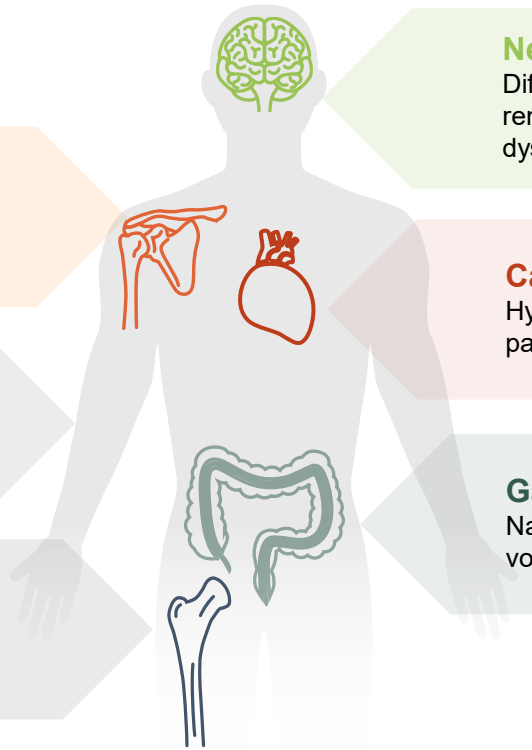
NDA accepted for bezuclastinib in imatinib-resistant or intolerant GIST; **November 30, 2026 PDUFA date** assigned

BEZUCLASTINIB in Systemic Mastocytosis



Bezuclastinib is an oral, potent, and selective type 1 TKI with activity against *KIT* p.D816V, the activating mutation in most patients with systemic mastocytosis[1-5]

Symptoms of NonAdvSM



Neurocognitive
Difficulty concentrating, difficulty remembering, brain fog, cognitive dysfunction, anxiety, depression

Fatigue
Tiredness

Cardiovascular
Hypotension, tachycardia, palpitations, chest tightness

Skin
Itching, flushing, skin redness, spots

Gastrointestinal
Nausea, abdominal pain, diarrhea, vomiting, bloating, GERD

Pain
Headache, bone pain, joint pain

- Nonadvanced SM (NonAdvSM), including indolent SM, smoldering SM, and bone marrow mastocytosis subtypes, is the most prevalent form of SM[3,6,7]
- NonAdvSM can be associated with debilitating symptoms, including life-threatening anaphylaxis, which can significantly impair quality of life[5,8,9]
- Bezuclastinib is highly active against *KIT* p.D816V, has minimal brain penetration and spares closely related kinases, which may minimize off-target toxicities, such as bleeding, cognitive impairment, edema, and pleural effusion[1,2,10]

GERD, gastroesophageal reflux disease; SM, systemic mastocytosis; TKI, tyrosine kinase inhibitor.

1. DeAngelo DJ, et al. *Hemasphere.* 2022; 6(suppl). **2**. Guarnieri A, et al. Poster presented at: AACR Annual Meeting; April 8-13, 2022; Orleans, LA. **3.** Ungerstedt J, et al. *Cancers.* 2022;14(16):3942. doi:10.3390/cancers14163942 **4.** Li JY, et al. *Cancers (Basel).* 2023.15(23). **5.** Tse KY, et al. *J Allergy Clin Immunol Glob.* 2024.3(4):100316. **6.** Scherber RM and Borate U. *Br J Haematol.* 2018;180:11-23. **7.** Gilreath JA, et al. *Clin Pharmacol.* 2019;11:77-92. **8.** Pardanani A. *Am J Hematol.* 2021;96(4):508-25. **9.** Piris-Villaespesa M and Alvarez-Twose I. *Front Pharmacol.* 2020;11(443): doi: 10.3389/fphar.2020.00443. **10.** Das A, et al. *Crit Rev Oncol Hematol.* 2021;157:103186.

KIT MUTANT COMPETITIVE LANDSCAPE

Minimal Late-Stage Competitive Activity with Clear Path to Best-in-Class Position

		Systemic Mastocytosis		
		avapritinib	**elenestinib**	**bezuclastinib**
	D816V potent	✓	✓	✓
	CNS selective	✗	✓	✓
	PDGFR sparing	✗	✗	✓
	FLT3/CSF1R sparing	✗	✗	✓
Active trials	**ASM**	Approved	Phase 1/2	NDA Submitted June 2026
	NonAdvSM	Approved	Phase 2/3	NDA Accepted; 12/30/26 PDUFA

Expanded Results From the Phase 2 Summit Trial: Bezuclastinib in Adults With Non-Advanced Systemic Mastocytosis

Nathan A Boggs[1], Lindsay Rein[2], Prithviraj Bose[3], Brian D Modena[4], Vito Sabato[5], Karin Hartmann[6], Cem Akin[7], Tracy I George[8], Cecilia Arana Yi[9], Hanneke Oude Elberink[10], Deepti H Radia[11], Andreas Reiter[12], Miguel Piris-Villaespesa[13], Ingunn Dybedal[14], Jens Panse[15,16], Stephen T Oh[17], Pankit Vachhani[18], Anthony M Hunter[19], Mariana Castells[20], Cristina Livideanu[21], Paul van Daele[22], Arnold Kirshenbaum[23], Iván Alvarez-Twose[24], Jennifer E Vaughn[25], Minakshi Taparia[26], Sonia Cerquozzi[27], Andrzej Mital[28], Marek Hus[29], Alessandra Romano[30], John M Fahrenholz[31], Frederick Lansigan[32], Cristina Papayannidis[33], Helena Pomares-Marin[34], Michela Rondoni[35], Celalettin Ustun[36], Richard Herrscher[37], Amanda Pilla[38], Jenna Zhang[38], Lei Sun[38], Nisha Shah[38], Hina Jolin[38], Rachael Easton[38], Jessica Sachs[38], Frank Siebenhaar[39,40], Daniel J DeAngelo[41]

[1]Department of Medicine, Uniformed Services University & Walter Reed National Military Medical Center, Bethesda, MD, USA; [2]Duke Cancer Institute, Durham, NC, USA; [3]MD Anderson Cancer Center, Houston, TX, USA; [4]Modena Allergy and Asthma, La Jolla, CA, USA; [5]Antwerp University Hospital (UZA), Edegem, Belgium; [6]University Hospital Basel and University of Basel, Basel, Switzerland; [7]University of Michigan, Ann Arbor, MI, USA; [8]Huntsman Cancer Institute, University of Utah, ARUP Laboratories, Salt Lake City, UT, USA; [9]Mayo Clinic Arizona, Phoenix, AZ, USA; [10]University Medical Center Groningen, Groningen Research Institute of Asthma and COPD, University of Groningen, Groningen, The Netherlands; [11]Guy's & St Thomas' Hospitals NHS Foundation Trust, London, UK; [12]Universitätsmedizin Mannheim, Mannheim, Germany; [13]Ramón y Cajal Hospital, Madrid, Spain; [14]Oslo University Hospital, Oslo, Norway; [15]Center for Integrated Oncology Aachen Bonn Cologne Düsseldorf (CIO ABCD), Aachen, Germany; [16]Department of Hematology, Oncology, Hemostaseology and Stem Cell Transplantation, University Hospital RWTH Aachen, Aachen, Germany; [17]Washington University School of Medicine, St. Louis, MO, USA; [18]University of Alabama at Birmingham, Birmingham, AL, USA; [19]Emory University School of Medicine, Atlanta, GA, USA; [20]Brigham and Women's Hospital, Boston, MA, USA; [21]CHU de Toulouse, Hopital Larrey, Toulouse, France; [22]Erasmus Medical Center, Rotterdam, The Netherlands; [23]Allervie, Glenn Dale, MD, USA; [24]Instituto de Estudios de Mastocitosis de Castilla-La Mancha, Hospital Virgen del Valle, Toledo, Spain; [25]The Ohio State University, Columbus, OH, USA; [26]University of Alberta, Edmonton, Alberta, Canada; [27]University of Calgary, Calgary, AB, Canada; [28]Uniwersyteckie Centrum Kliniczne, Klinika Hematologii I Transplantologii, Gdnask, Poland; [29]Department of Hematooncology and Bone Marrow Transplantation, Medical University of Lublin, Lublin, Poland; [30]Azienda Ospedaliero Universitaria Policlinico Rodolico San Marco, Catania, Italy; [31]Vanderbilt University Medical Center, Nashville, TN, USA; [32]Dartmouth Cancer Center, Lebanon, NH, USA; [33]IRCCS Azienda Ospedaliero-Universitaria di Bologna, Policlinico di Sant'Orsola, Bologna, Italy; [34]Institut Catala d'Oncologia L'Hospitalet, Barcelona, Spain; [35]Azienda Unità Sanitaria Locale della Romagna, Ospedale S.Maria delle Croci, Ravenna, Italy; [36]Rush University Medical Center, Chicago, IL, USA; [37]AirCare, Plano, TX, USA; [38]Cogent Biosciences Inc., Waltham, MA, USA; [39]Institute of Allergology, Charité-Universitaetsmedizin Berlin, Berlin, Germany; [40]Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Immunology and Allergology IA, Berlin, Germany; [41]Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, MA, USA

Presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) 2026 Annual Meeting | February 28, 2026 | Philadelphia, PA, USA

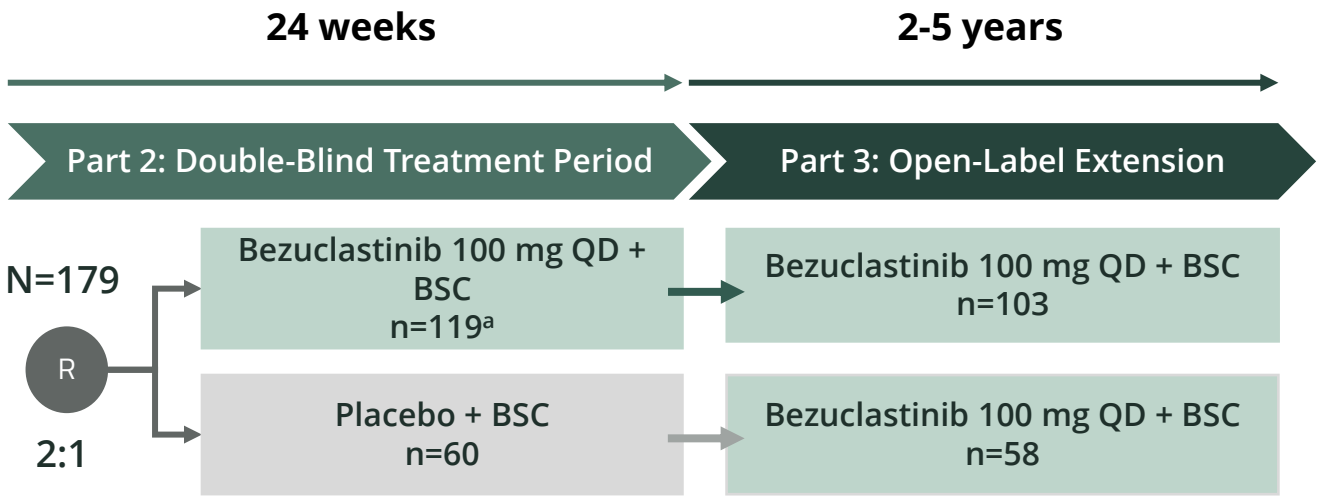
Summit (NCT05186753): Pivotal phase 2 multicenter, randomized, double-blind, placebo-controlled study evaluating bezuclastinib in NonAdvSM

Eligibility

ISM, BMM, or SSM based on WHO 2022 classification

Inadequate symptom control (moderate to severe symptoms) despite ≥2 anti-mediator therapies

BSC medications include H1RA, H2RA, cromolyn, LTRAs, corticosteroids, omalizumab, and PPIs



Part 3 OLE Objectives

- Characterize long-term safety and tolerability of bezuclastinib
- Durability of effect at the selected dose
- Change of the most severe symptom and most severe subdomain of MS2D2
- Evaluate additional efficacy parameters in patients with NonAdvSM
- Determine the effects of bezuclastinib on serum tryptase
- Explore changes in concomitant medication use for the treatment of NonAdvSM

[a]One patient withdrew consent and did not receive treatment.

BM, bone marrow; BMM, bone marrow mastocytosis; BSC, best supportive care; H1RA, histamine receptor type 1 antagonist; HR2A, histamine receptor type 2 antagonist; ISM, indolent SM; LTRA, leukotriene receptor antagonists; MC, mast cell; MS2D2, mastocytosis symptom severity daily diary; NonAdvSM, non-advanced systemic mastocytosis; PPI, proton pump inhibitors; QD, once daily; R, randomized; SSM, smoldering SM; TSS, total symptom score; VAF, variant allele frequency; WHO, World Health Organization.

SLIDES ARE INTENDED FOR USE IN THE ORDER THEY ARE PRESENTED, WITH NO EDITS

Patient demographics and characteristics were representative of a broad NonAdvSM population

Baseline Characteristics	Bezuclastinib 100 mg QD (N=119)	Placebo (N=60)
Female, n (%)	**74 (62.2)**	**44 (73.3)**
Median age in years, (range)	**51 (24–73)**	**52 (23–78)**
NonAdv subtype, n (%)		
Indolent SM	**97 (81.5)**	**50 (83.3)**
Smoldering SM	**8 (6.7)**	**4 (6.7)**
BM mastocytosis	**14 (11.8)**	**6 (10.0)**
Region, n (%)		
North America	**53 (44.5)**	**28 (46.7)**
Europe	**64 (53.8)**	**30 (50.0)**
Asia-Pacific	**2 (1.7)**	**2 (3.3)**
SM therapy		
Prior KIT inhibitor[a], n (%)	**17 (14.3)**	**5 (8.3)**
Best supportive care medications, median (range)	**3 (0–6)**	**3 (1–7)**

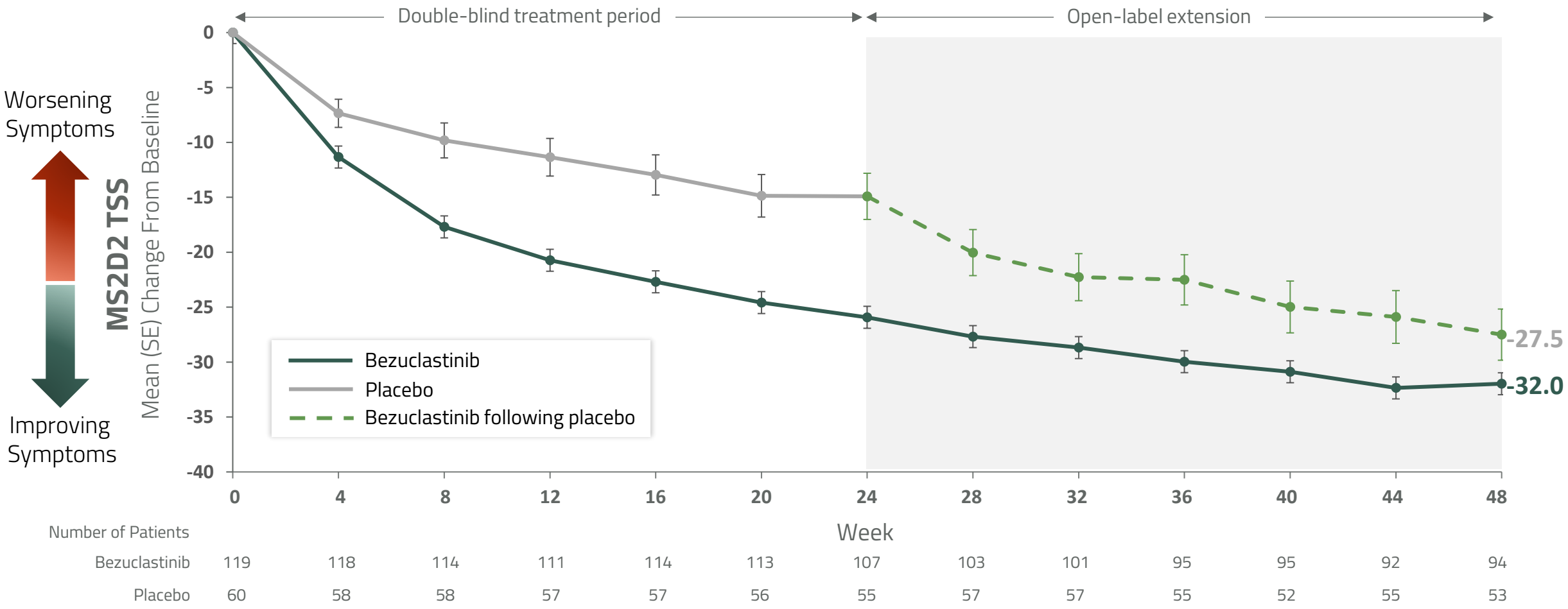
Disease Severity	Bezuclastinib 100 mg QD (N=119)	Placebo (N=60)
Mean MS2D2 TSS, (range)	**57.1 (18–105.2)**	**52.6 (12.8–91.3)**
***KIT* p.D816V[b] in whole blood, detected, n (%)**	**91 (76.5)**	**48 (80.0)**
Median *KIT* p.D816V VAF[b], % (range)	**0.22 (0[c]–32.3)**	**0.30 (0[c]–33.6)**
Median bone marrow MC burden, % (range)	**10 (1–75)**	**10 (1–75)**
Median serum tryptase, ng/mL (range)	**39.9 (6.3–448.0)**	**41.2 (7.1–692.0)**
Serum tryptase <20 ng/mL, n (%)	**22 (18.2)**	**10 (16.7)**
Most severe MS2D2 TSS symptoms at baseline in >10% of patients, n (%)		
Tiredness	**54 (45.4)**	**24 (40.0)**
Spots	**39 (32.8)**	**21 (35.0)**
Bone pain	**16 (13.4)**	**9 (15.0)**

[a]KIT inhibitors included avapritinib, imatinib, midostaurin, dasatinib, and masitinib. [b]Limit of detection equals 0.03%. [c]Undetected.
BM, bone marrow; MC, mast cell; MS2D2, mastocytosis symptom severity daily diary; NonAdvSM, nonadvanced SM; QD, once daily; SM, systemic mastocytosis; TSS, total symptom score; VAF, variant allele frequency.

SLIDES ARE INTENDED FOR USE IN THE ORDER THEY ARE PRESENTED, WITH NO EDITS

Rapid, durable, and clinically meaningful symptom improvement that continues to deepen to 48 weeks of treatment

Patients crossing over to receive active treatment experience clinically meaningful symptom improvement



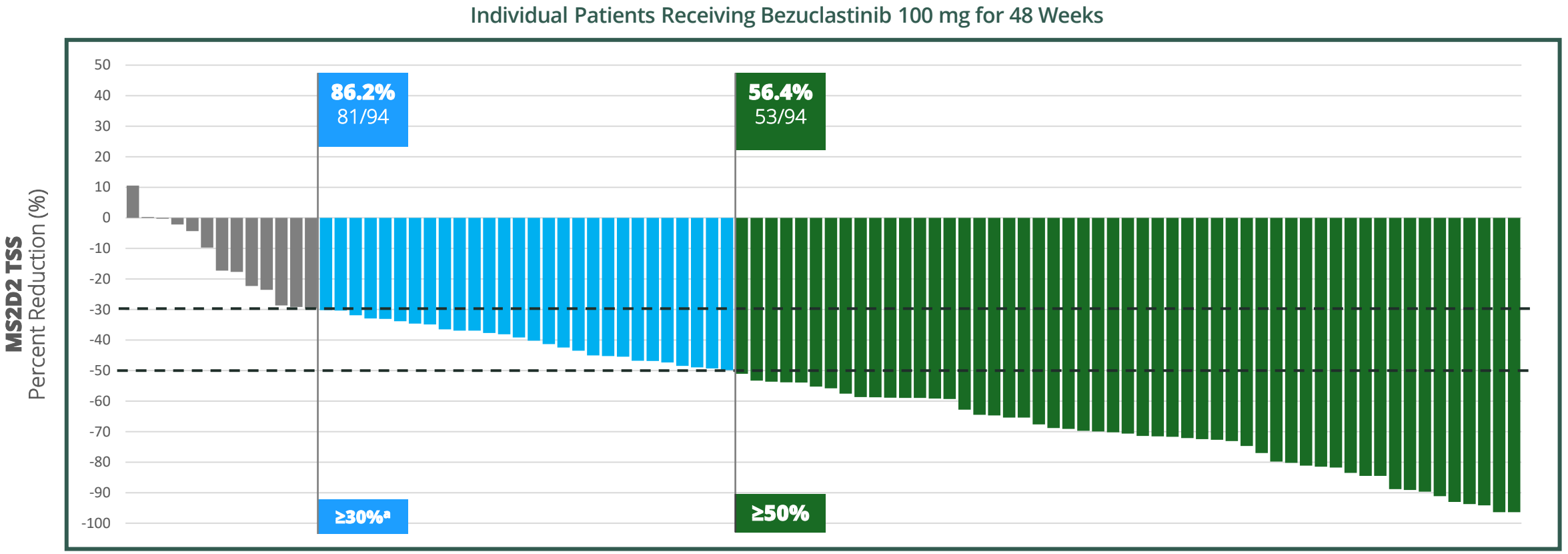
MS2D2, mastocytosis symptom severity daily diary; SE, standard error; TSS, total symptom score.

Data cutoff: Nov 7, 2025.

SLIDES ARE INTENDED FOR USE IN THE ORDER THEY ARE PRESENTED, WITH NO EDITS

Bezuclastinib achieves robust symptom reduction at 48 weeks

86% of Patients Achieve Clinically Meaningful Symptom Improvement



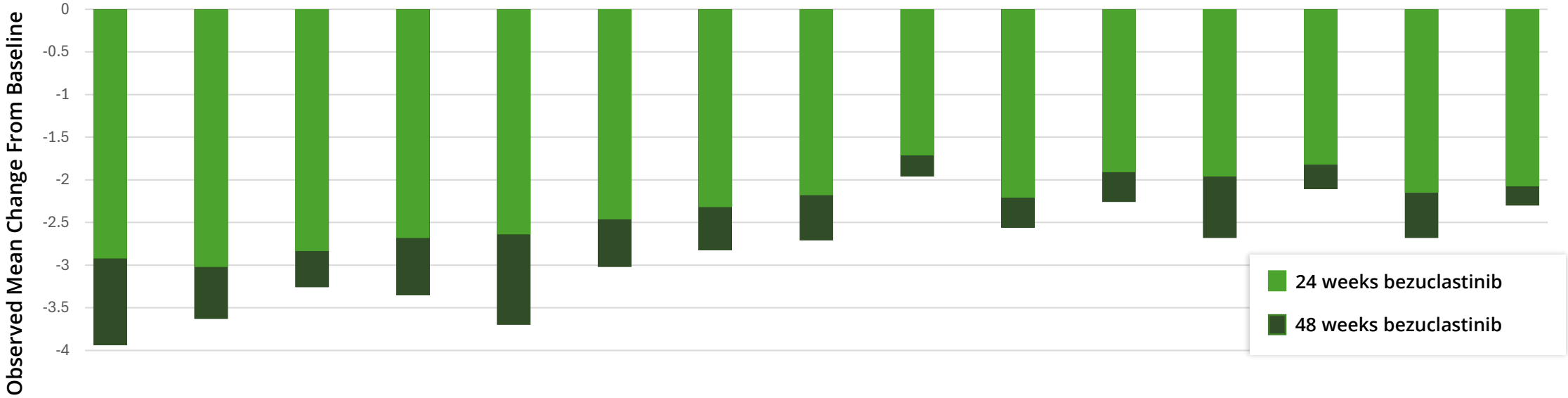
[a]Symptom reductions of ≥30% represent clinically meaningful change as determined by anchor-based analyses.

Data cutoff: November 7, 2025

SLIDES ARE INTENDED FOR USE IN THE ORDER THEY ARE PRESENTED, WITH NO EDITS

Bezuclastinib achieves sustained and deepening symptom improvement through 48 weeks in NonAdvSM

	Symptoms in MS2D2 Total Symptom Score											Additional MS2D2 Symptoms		
	Most Severe Symptom	Skin				Fatigue	Neurocognitive		Other					
		Itching	Flushing	Skin redness	Spots	Tiredness	Concentration	Remembering	Nausea	Abdominal pain	Headache	Bone pain	Diarrhea severity	Brain fog	Dizziness
Mean score at baseline	8.1	5.2	5.1	5.2	6.0	7.3	5.7	5.5	3.3	4.3	4.0	5.6	3.0	5.3	3.4



- All symptoms have deepening of improvement to 48 weeks of treatment with bezuclastinib
- At week 48, 50% of those in the bezuclastinib arm had a dose reduction or discontinuation of BSC medication

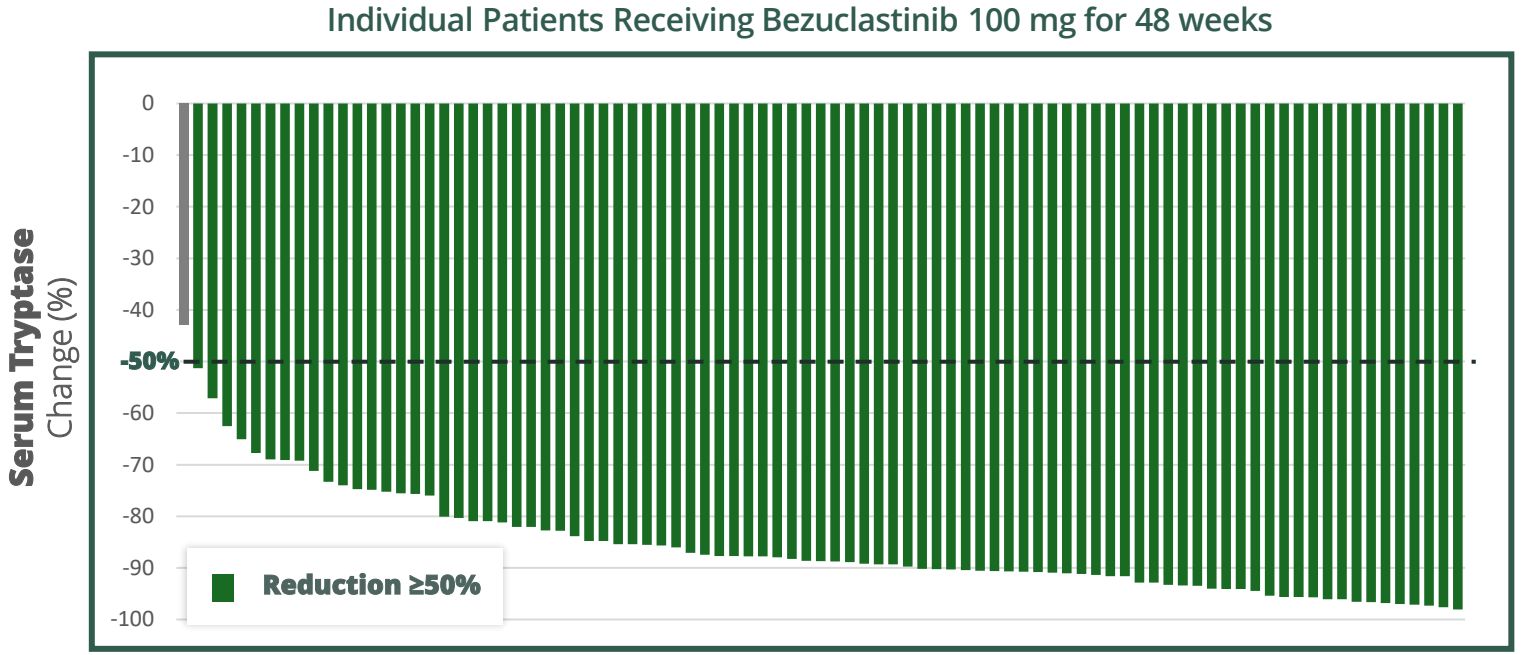
MS2D2, mastocytosis symptom severity daily diary; TSS, total symptom score.

Data cutoff: Nov 7, 2025.

SLIDES ARE INTENDED FOR USE IN THE ORDER THEY ARE PRESENTED, WITH NO EDITS

99% of patients reached ≥50% reduction in serum tryptase at 48 weeks

Serum tryptase normalization persisted to 48 weeks of bezuclastinib treatment



		Week 48	
		Bezuclastinib N=89	Placebo → Bezu N=60
Median serum tryptase, ng/mL (range)		**4.7** (1.0-128.0)	**5.8** (1.1-143.0)
Patients reaching ≥50% reduction in serum tryptase, % (n/N)[a]		**98.9%** (88/89)	**96.1%** (49/51)
Patients achieving threshold[b], % (n/N)	<20 ng/mL	**91.7** (66/72)	**90.5** (38/42)
	<11.4 ng/mL	**83.3** (70/84)	**77.6** (38/49)

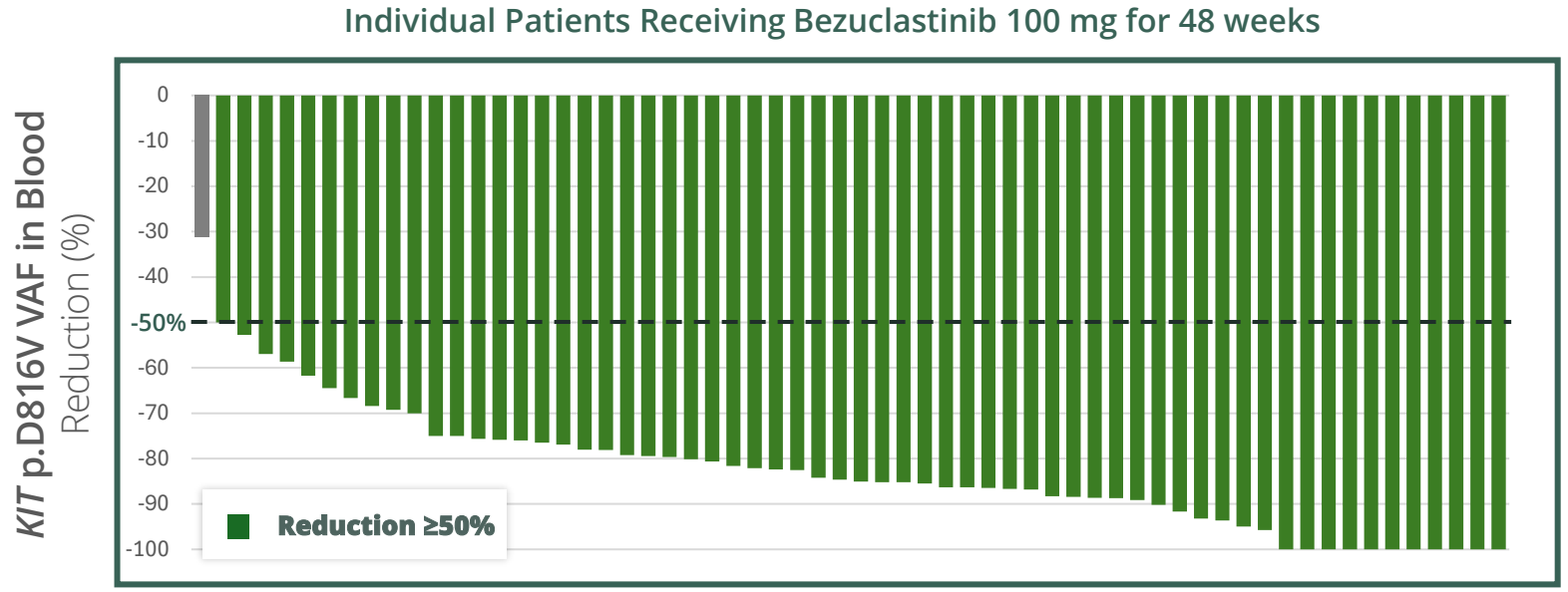
- At week 48, the majority of placebo crossover patients achieved ≥50% serum tryptase reductions and normalization within 24 weeks of bezuclastinib treatment

[a]Patients with data at 48 weeks. [b]Of patients with baseline serum tryptase above threshold.
ITT, intention to treat.

Data cutoff: Nov 7, 2025.

SLIDES ARE INTENDED FOR USE IN THE ORDER THEY ARE PRESENTED, WITH NO EDITS

Bezuclastinib significantly reduced *KIT* p.D816V variant allele frequency, a molecular driver of disease, at 48 weeks



		Week 48	
		Bezuclastinib	Placebo → Bezu
Median *KIT* p.D816V VAF in blood, % (range)		**0.04** (0-10.5)	**0.07** (0-12.1)
Patients reaching ≥50% reduction in KIT p.D816V VAF[a] in blood[b] or undetectable mutation, % (n/N)	ITT population	**98.4** (61/62)	**100** (37/37)

- At week 48, placebo crossover patients achieved significant reductions in *KIT* p.D816V within 24 weeks of bezuclastinib treatment

[a]Patients with data at 48 weeks. [b]Limit of detection equals 0.03%.
ITT, intention to treat; VAF, variant allele frequency.

Data cutoff: Nov 7, 2025.

SLIDES ARE INTENDED FOR USE IN THE ORDER THEY ARE PRESENTED, WITH NO EDITS

Bezuclastinib was well tolerated and no new safety concerns observed with longer-term treatment

TEAEs during OLE	Placebo → Bezuclastinib (n=58)		Bezuclastinib (n=103)	
Median (range) duration of bezuclastinib treatment (months) in the OLE	8.8 (2.8 – 14.4)		8.6 (0.46 – 15.0)	
TEAEs, n (%)	57 (98.3)		92 (89.3)	
Serious TRAEs, n (%)	1 (1.7)		0	
Reductions due to TRAEs, n (%)	9 (15.5)		2 (1.9)	
DCs due to TRAEs, n (%)	3 (5.2)		1 (1.0)	
TEAEs ≥10% either arm, n (%)				
Preferred Term	**All Grade**	**Grade ≥ 3**	**All Grade**	**Grade ≥ 3**
Hair color changes	37 (63.8)	-	11 (10.7)	-
ALT/AST increased[a]	22 (37.9)	5 (8.6)	10 (9.7)	1 (1.0)
Altered taste[a]	12 (20.7)	-	2 (1.9)	-
Dizziness	9 (15.5)	-	10 (9.7)	-
Nausea	8 (13.8)	-	5 (4.9)	-
Dyspepsia	8 (13.8)	-	5 (4.9)	-
Headache	8 (13.8)	-	9 (8.7)	-
URTI	8 (13.8)	-	7 (6.8)	-
Fatigue	8 (13.8)	2 (3.4)	2 (1.9)	-
Diarrhea	7 (12.1)	-	8 (7.8)	-
ALP increased	7 (12.1)	-	1 (1.0)	-
Arthralgia	6 (10.3)	-	10 (9.7)	1 (1.0)
Insomnia	6 (10.3)	-	4 (3.9)	-

- The majority of TEAEs were low grade and reversible
- Overall median (range) duration of treatment in patients continuing bezuclastinib in the OLE was 13.4 (0.67–20.5) months
- Consistent safety and tolerability profile observed in OLE for patients crossing over to bezuclastinib, similar to the previously reported 24-week experience
- The only hepatic events reported were transient and manageable lab abnormalities, similar to the previously reported 24-week experience
- Discontinuations due to TRAEs remained limited, consistent with the previously reported 24-week experience; all were due to transaminase elevations and all events fully resolved

Only TEAEs that occurred during OLE on bezuclastinib treatment are included. Adverse events per NCI CTCAE v5.0.

[a]Includes pooled terms.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; DC, discontinuation; TEAE, treatment emergent adverse event; TRAE, treatment related adverse event.

Data cutoff: Nov 07, 2025

Bezuclastinib represents a promising new treatment for patients with NonAdvSM

Disease modification and symptom improvement continue out to 48 weeks of treatment

Rapid, statistically significant, and **clinically meaningful symptom improvement** is durable and continues to deepen to 48 weeks of treatment

- Placebo patients crossing over to receive bezuclastinib experience clinically meaningful symptom improvement

86% of patients achieve clinically meaningful symptom improvement

- All symptoms have deepening of improvement to 48 weeks of treatment with bezuclastinib
- At week 48, 50% in the bezuclastinib arm had a dose reduction or discontinuation of BSC medication



Safety and tolerability profile in OLE, with > 24 weeks and up to 48 weeks of treatment, supports potential for chronic dosing

NDA for broad NonAdvSM population accepted; assigned 12/30/26 PDUFA BTD granted by the FDA for patients with NonAdvSM previously treated with avapritinib and with smoldering SM

Bezuclastinib Systemic Mastocytosis Expanded Access Program (NCT06915766) is currently open to requests from treating physicians in the United States

FDA, US Food and Drug Administration; NDA, new drug application; NonAdvSM, non-advanced SM; SM, systemic mastocytosis; TEAE, treatment-emergent adverse event; TSS, total symptom score.

cogent BIOSCIENCES

Advanced Systemic Mastocytosis



Efficacy and Safety of Bezuclastinib in Patients With Advanced Systemic Mastocytosis: Results From the Apex Study

Daniel J. DeAngelo[1], Deepti H. Radia[2], Tracy I. George[3], Isaac Goncalves[4], Khalid Shoumariyeh[5], Cristina Papayannidis[6], Pankit Vachhani[7], Tsewang Tashi[8], Anthony M. Hunter[9], Vinod Pullarkat[10], Juliana Schwaab[11], Jonathan Lambert[12], Miguel Piris-Villaespesa[13], Prithviraj Bose[14], Cecilia Arana Yi[15], Tania Jain[16], Gabriela S. Hobbs[17], Andreas Reiter[18], Karin Hartmann[19], Stephanie Lee[20], Marek Hus[21], Sudipto Mukherjee[22], Wolfgang R. Sperr[23], Stephen Fuller[24], Saskia K. Klein[25], Cristina Bulai Livideanu[26], Jens Panse[27], Olivier Hermine[28], Manish Jain[29], Minakshi Taparia[30], Ewa Wierzbicka-Hainaut[31], Kelli W. Williams[32], Helena Pomares-Marin[33], Gary Schiller[34], Amanda Pilla[35], Kim Dishman[35], Jenna Zhang[35], Lei Sun[35], Deepak Nagendra[35], Rachael Easton[35], Jessica Sachs[35], Jason Gotlib[36]

1. Dana-Farber Cancer Institute, Boston, MA, USA; 2. Guy's and St. Thomas' NHS Foundation Trust, London, UK; 3. University of Utah, ARUP Laboratories, Salt Lake City, UT, USA; 4. Royal Melbourne Hospital, Parkville, Australia; 5. Medical Center, Faculty of Medicine, University of Freiburg, Freiburg, Germany; 6. IRCCS Azienda Ospedaliero-Universitaria di Bologna, Istituto di Ematologia “Seràgnoli,“ Bologna, Italy; 7. University of Alabama at Birmingham, Birmingham, AL, USA; 8. Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA; 9. Emory University School of Medicine, Atlanta, GA, USA; 10. City of Hope, Duarte Cancer Center, Duarte, CA, USA; 11. University Hospital Mannheim, Heidelberg University, Mannheim, Germany; 12. University College Hospital, University College of London Hospitals NHS Foundation Trust, London, UK; 13. Hospital Universitario Ramón y Cajal, Madrid, Spain; 14. The University of Texas MD Anderson Cancer Center, Houston, TX, USA; 15. Mayo Clinic, Phoenix, AZ, USA; 16. Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins University, Baltimore, MD, USA; 17. Massachusetts General Brigham, Boston, MA, USA; 18. University Hospital Mannheim, Heidelberg University, Mannheim, Germany; 19. University Hospital Basel and University of Basel, Basel, Switzerland; 20. St. Michael’s Hospital, Toronto, Canada; 21. Medical University of Lublin, Lublin, Poland; 22. Cleveland Clinic Taussig Cancer Institute, Cleveland, OH, USA; 23. Ludwig Boltzmann Institute for Hematology and Oncology, Medical University of Vienna, Vienna, Austria; 24. Sydney Medical School, Nepean Clinical School, University of Sydney, Kingswood, Australia; 25. University Medical Center Groningen, University of Groningen, Groningen, the Netherlands; 26. Toulouse University Hospital, Toulouse, France; 27. RWTH Aachen University, Aachen, Germany; 28. Necker Children's Hospital, Paris Centre University, Paris, France; 29. The Leeds Teaching Hospital NHS Foundation Trust, Leeds, UK; 30. University of Alberta, Edmonton, AB, Canada; 31. Université de Poitiers, CHU de Poitiers, LITEC, Poitiers, France; 32. Medical University of South Carolina, Charleston, SC, USA; 33. Institut Català d’Oncologia L’Hospitalet – Hospital Duran i Reynals, Barcelona, Spain; 34. David Geffen School of Medicine, University of California, Los Angeles, CA, USA; 35. Cogent Biosciences, Inc., Waltham, MA, USA; 36. Stanford University School of Medicine, Stanford, CA, USA.

Unmet Need Remains for Patients with Advanced Systemic Mastocytosis (AdvSM)

- AdvSM, a rare myeloid neoplasm, is an aggressive and life-threatening form of SM driven by the *KIT* p.D816V mutation in most patients[1-4]
  - Leads to increased production and accumulation of neoplastic mast cells (MC), organ damage and dysfunction from MC infiltration, and decreased overall survival[1,2]
  - Subtypes: aggressive SM (ASM), SM with associated hematologic neoplasm (SM-AHN), mast cell leukemia (MCL)[4]
- Current approved therapies for AdvSM have limitations in efficacy, safety, and durability[3-8]
- Bezuclastinib is an investigational, oral, highly selective tyrosine kinase inhibitor with potent activity against KIT D816V
- The Apex study (NCT04996875) evaluated the efficacy and safety of bezuclastinib in patients with AdvSM; **here, we present results from the pivotal portion of Apex**

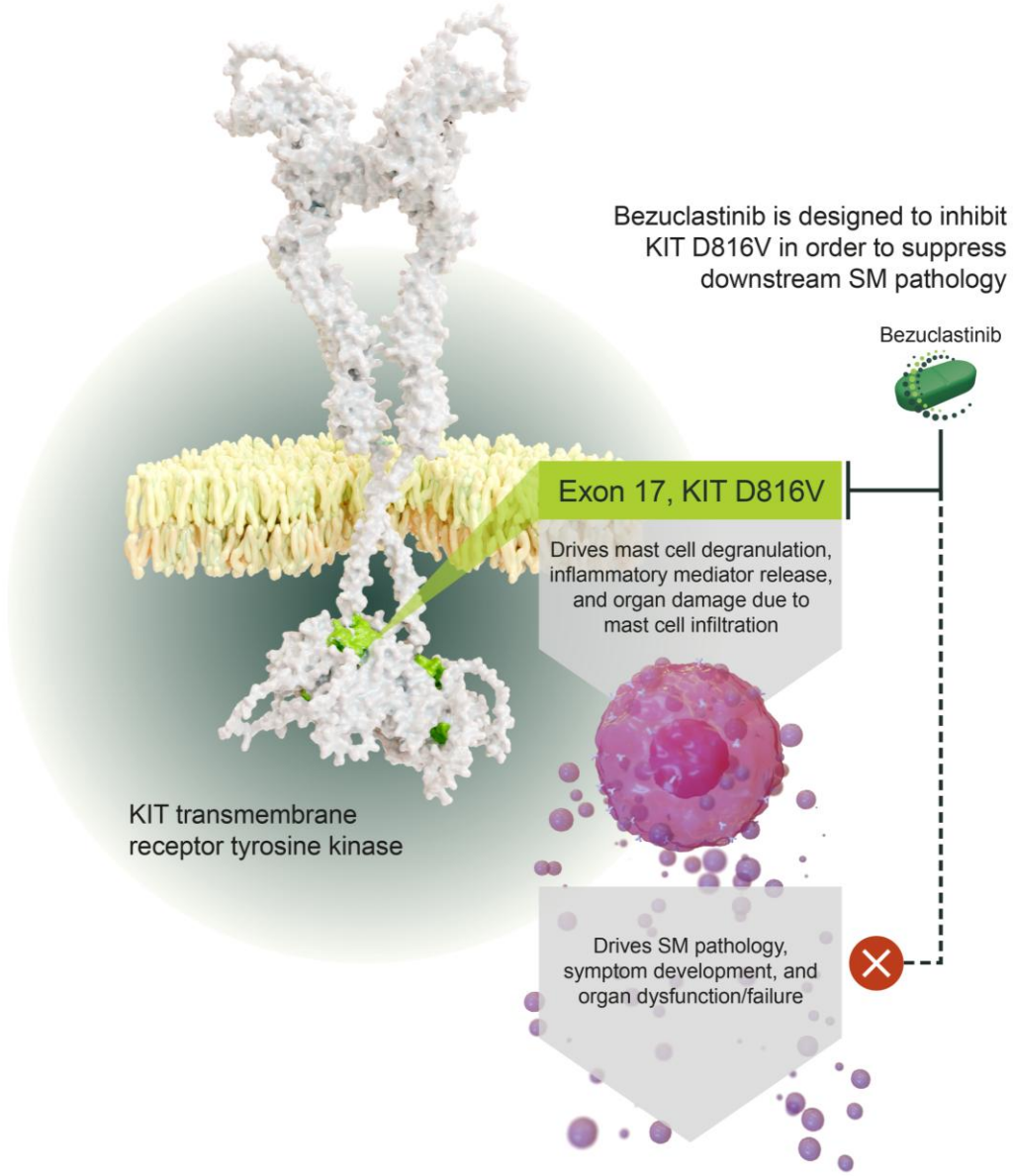


Figure developed by Cogent Biosciences, Inc.

AdvSM, advanced SM; MC, mast cell; SM, systemic mastocytosis.

1. Pardanani A, *Am J Hematol.* 2021;96(4):508-525. **2.** DeAngelo DJ, et al. *Nat Med.* 2021;27(12):2183-2191. **3.** Gotlib J, et al. *N Engl J Med.* 2016;374(26):2530-2541. **4.** Lübke J, et al. *J Clin Oncol.* 2022;40(16):1783-1794. **5.** RYDAPT (midostaurin) [package insert]. Novartis Pharmaceuticals; 2021. **6.** AYVAKIT (avapritinib) [package insert]. Blueprint Medicines Corporation; 2021. **7.** Rossignol J, et al. *Hematol Oncol.* 2022;40(5):1030-1040. **8.** Magliacane D, et al. *Transl Med UniSa.* 2014;8:65-74.

Bezuclastinib is an Investigational, Oral, Highly Selective Tyrosine Kinase Inhibitor with Potent Activity Against KIT D816V

- From nonclinical studies, bezuclastinib[1,2]
  - Has high activity with specificity for mutations in *KIT* exons 11, 17, and 18
  - Spares closely related kinases, which may minimize off-target toxicities such as bleeding, edema, and pleural effusion
  - Demonstrates minimal brain penetration, which may reduce risk for CNS-related adverse events

Kinase Inhibition Profile of Investigational and Approved KIT Inhibitors for Systemic Mastocytosis; Cell IC_{50} (nM)

Compound	KIT V560G/D816V	WT KIT	PDGFRα	PDGFRβ	CSF1R	FLT3	KDR
Bezuclastinib	**14**	**114**	**>10,000**	**>10,000**	**>10,000**	**>1000**	**>1000**
Avapritinib	13	76	53	11	447	400	>1000
Elenestinib	5	231	20	17	161	453	>1000
Midostaurin	244	182	301	88	542	17	>1000
Imatinib	>1000	424	75	247	611	>1000	>1000

Within 10× potency of KIT D816V | Within 5× potency of KIT D816V | Potency > KIT D816V

CNS, central nervous system; CSF1R, colony-stimulating factor 1 receptor; FLT3, FMS-like tyrosine kinase 3; IC_{50}, half-maximal inhibitory concentration; KDR, kinase insert domain receptor; KIT, KIT proto-oncogene, receptor tyrosine kinase; PDGFRα, platelet-derived growth factor receptor α; PDGFRβ, platelet-derived growth factor receptor β; WT, wild type.

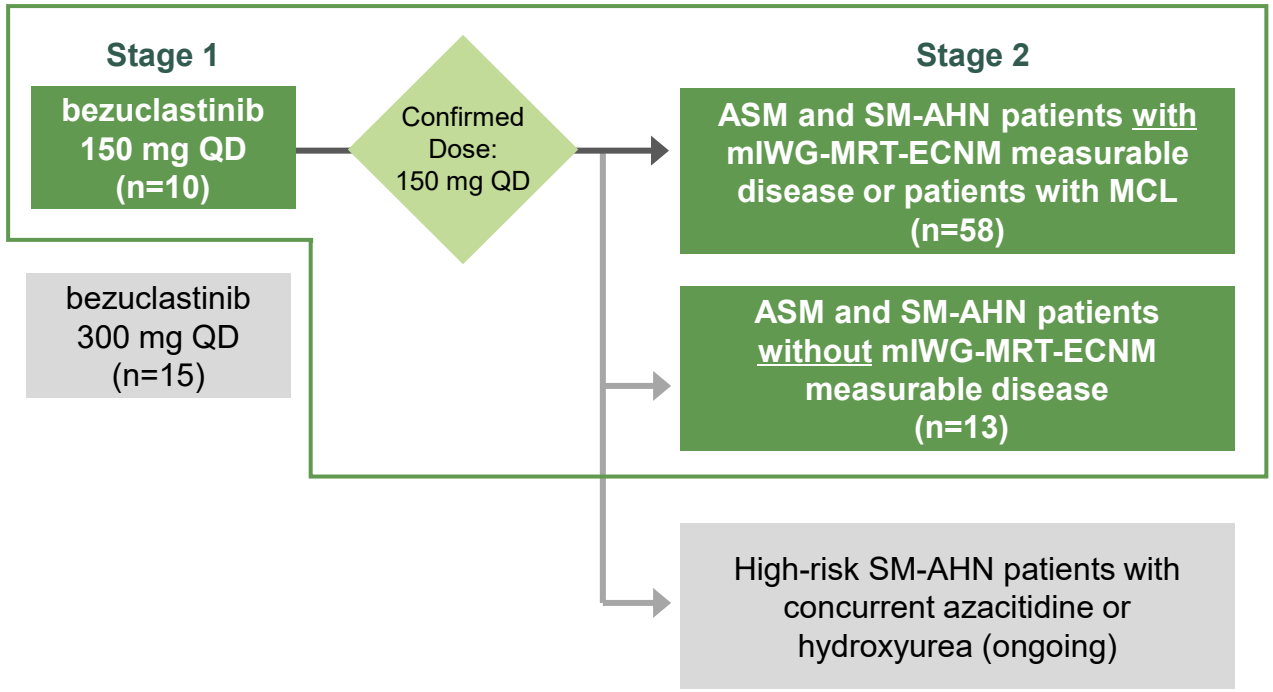
1. Guarnieri A, et al. *Mol Cancer Ther*. 2021;20(12 Suppl):P257. Abstract P257. AACR Annual Meeting 2022. 2. Crow M, et al. *Blood*. 2025;146(Suppl 1):5531. ASH Annual Meeting 2025.

Apex (NCT04996875): Phase 2, Multipart, Multicenter, Open-Label Study of Bezuclastinib in Patients with AdvSM

PART 2: PIVOTAL TRIAL (N=81)

Key Eligibility[a]

- ASM, SM-AHN, or MCL per WHO 2022 Classification
- No restrictions on prior therapy
- Serum tryptase ≥20 ng/mL
- Platelet count ≥50×10^9/L



Part 2 Endpoints

Primary:

- ORR (CR/CRh + PR + CI) per mIWG-MRT-ECNM criteria

Key Secondary:

- ORR (CR/CRh + PR) per Pure Pathologic Response (PPR) criteria

Other Secondary[a]:

- Time to response (TTR)
- Duration of response (DOR)
- Changes in objective measures of disease
  - Bone marrow mast cell burden
  - Serum tryptase
  - *KIT* p.D816V variant allele frequency
- Progression-free survival (PFS)
- Overall survival (OS)
- Safety/tolerability

[a]Additional criteria and endpoints are defined in the protocol.

AdvSM, advanced SM; ASM, aggressive SM; CI, clinical improvement; CR, complete remission; CRh, CR with partial hematologic recovery; MCL, mast cell leukemia; mIWG-MRT-ECNM, modified International Working Group–Myeloproliferative Neoplasms Research and Treatment–European Competence Network on Mastocytosis; ORR, overall response rate; PPR, Pure Pathologic Response; PR, partial remission; QD, once daily; SM, systemic mastocytosis; SM-AHN, SM with associated hematologic neoplasm; WHO, World Health Organization.

Baseline Characteristics

Characteristic		Bezuclastinib 150 mg QD (N=81)
Female, n (%)		23 (28)
Median age, years (range)		70 (43–87)
ECOG Performance Status, n (%)	0	22 (27)
	1	40 (49)
	≥2	19 (23)
AdvSM subtype per central eligibility review, n (%)	ASM	11 (14)
	SM-AHN[a]	57 (70)
	MCL[b]	13 (16)
Median bone marrow mast cell burden, % (range)		35 (3–95)
Median serum tryptase, ng/mL (range)		191 (23–1987)
Median *KIT* p.D816V VAF in peripheral blood, % (range)		6.7 (0–91.4)
KIT p.D816V VAF detected[c], n (%)		71 (90[d])
***SRSF2/ASXL1/RUNX1* mutation detected in peripheral blood, n (%)**		48 (59)
Prior TKI therapy for AdvSM or AHN, n (%)		28[e] (35)
Prior midostaurin		24 (30)
Prior avapritinib		6 (7)
Prior imatinib		3 (4)

Data cutoff: March 31, 2026.

[a]AHN subtypes: CMML (n=37), MDS (n=6), MPN (n=4), MDS/MPN-U (n=10). [b]Includes 2 with MCL-AHN (MDS-MLD). [c]Droplet digital PCR limit of detection=0.03%. [d]Of 79 with baseline assessment. [e]5 received 2 prior TKIs.

AdvSM, advanced SM; AHN, associated hematologic neoplasm; ASM, aggressive SM; CMML, chronic myelomonocytic leukemia; ECOG, Eastern Cooperative Oncology Group; MCL, mast cell leukemia; MDS, myelodysplastic syndrome; MDS/MPN-U, MDS/MPN unclassifiable; MLD, multilineage dysplasia; MPN, myeloproliferative neoplasm; QD, once daily; SM, systemic mastocytosis; TKI, tyrosine kinase inhibitor; VAF, variant allele frequency.

Bezuclastinib Demonstrated High Response Rates Across AdvSM Subtypes, per mIWG-MRT-ECNM Criteria

Best Overall Response, n (%)	All Evaluable Patients (N=68)	ASM (n=8)	SM-AHN (n=47)	MCL (n=13)
Overall Response Rate (CR+CRh+PR+CI)	**44 (65)**	**5 (63)**	**34 (72)**	**5 (38)**
CR+CRh+PR	**39 (57)**	**3 (38)**	**31 (66)**	**5 (38)**
CR+CRh	**16 (24)**	**0**	**14 (30)**	**2 (15)**
Complete Remission (CR)	7 (10)	0	6 (13)	1 (8)
CR with Partial Hematologic Recovery (CRh)	9 (13)	0	8 (17)	1 (8)
Partial Remission (PR)	23 (34)	3 (38)	17 (36)	3 (23)
Clinical Improvement (CI)	5 (7)	2 (25)	3 (6)	0
Stable Disease	21 (31)	3 (38)	12 (26)	6 (46)
Progressive Disease	2 (3)	0	0	2 (15)
Not Evaluable	1 (1)	0	1 (2)	0

- Median (range) treatment duration: 62.1 (6.7–135.3) weeks
- Median (range) time to first response (CR, CRh, PR, CI): 8.4 (7.8–44.3) weeks
- Median duration of response was not estimable at time of data cutoff

Data cutoff: March 31, 2026.

AdvSM, advanced SM; ASM, aggressive SM; CI, clinical improvement; CR, complete remission; CRh, CR with partial hematologic recovery; MCL, mast cell leukemia; mIWG-MRT-ECNM, modified International Working Group–Myeloproliferative Neoplasms Research and Treatment–European Competence Network on Mastocytosis; PR, partial remission; SM, systemic mastocytosis; SM-AHN, SM with associated hematologic neoplasm.

Bezuclastinib Demonstrated High Response Rates Across AdvSM Subtypes, per Pure Pathologic Response (PPR) Criteria

Best Overall Response, n (%)	All Evaluable Patients (N=81)	ASM (n=11)	SM-AHN (n=57)	MCL (n=13)
Overall Response Rate (CR+CRh+PR)	**66 (81)**	**9 (82)**	**51 (89)**	**6 (46)**
CR+CRh	**50 (62)**	**6 (55)**	**39 (68)**	**5 (38)**
Complete Remission (CR)	33 (41)	2 (18)	26 (46)	5 (38)
CR with Partial Hematologic Recovery (CRh)	17 (21)	4 (36)	13 (23)	0
Molecular CR/CRh[a]	20 (25)	1 (9)	18 (32)	1 (8)
Partial Remission (PR)	16 (20)	3 (27)	12 (21)	1 (8)
Stable Disease	14 (17)	1 (9)	6 (11)	7 (54)
Progressive Disease	0	0	0	0
Not Evaluable	1 (1)	1 (9)	0	0

- Median (range) treatment duration: 63.0 (1.0–135.3) weeks
- Median (range) time to first response (CR, CRh, PR): 8.3 (7.8–70.4) weeks
- Median duration of response was not estimable at time of data cutoff

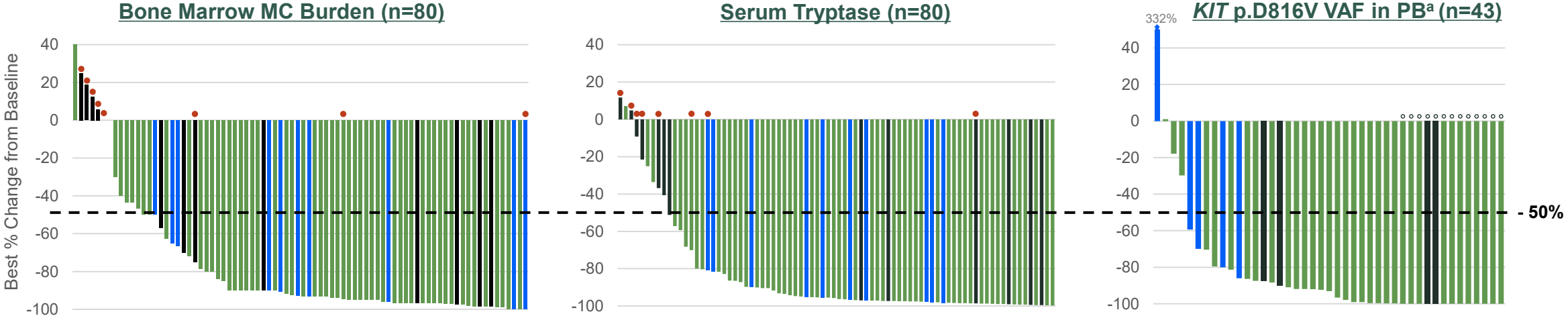
Data cutoff: March 31, 2026.

[a]Patients with molecular CR/CRh are a subset of those patients with overall CR/CRh who also achieved undetectable (<0.03%) levels of *KIT* p.D816V variant allele frequency.

AdvSM, advanced SM; ASM, aggressive SM; CR, complete remission; CRh, CR with partial hematologic recovery; MCL, mast cell leukemia; PPR, Pure Pathologic Response; PR, partial remission; SM, systemic mastocytosis; SM-AHN, SM with associated hematologic neoplasm.

Bezuclastinib Demonstrated Marked Reductions in Objective Measures of Disease in Patients with AdvSM

Individual Patients Receiving Bezuclastinib 150 mg QD



- **89%** achieved ≥50% reduction
  - Median time to 1st ≥50% reduction: 8.3 weeks
- **81%** (60/74) achieved clearance of MC aggregates
  - Median time to 1st clearance: 10.7 weeks

- **89%** achieved ≥50% reduction
  - Median time to 1st ≥50% reduction: 2.0 weeks
- **71%** achieved <20 ng/mL
  - Median time to 1st <20 ng/mL: 11.3 weeks
- **64%** achieved <11.4 ng/mL
  - Median time to 1st <11.4 ng/mL: 16.0 weeks

- **91%** achieved ≥50% reduction
  - Median time to 1st ≥50% reduction: 6.3 weeks
- **30%** achieved undetectable VAF
  - Median time to 1st undetectable VAF: 28.1 weeks

SM-AHN ASM MCL
KIT p.D816V VAF undetected in PB at baseline
KIT p.D816V VAF undetected in PB postbaseline

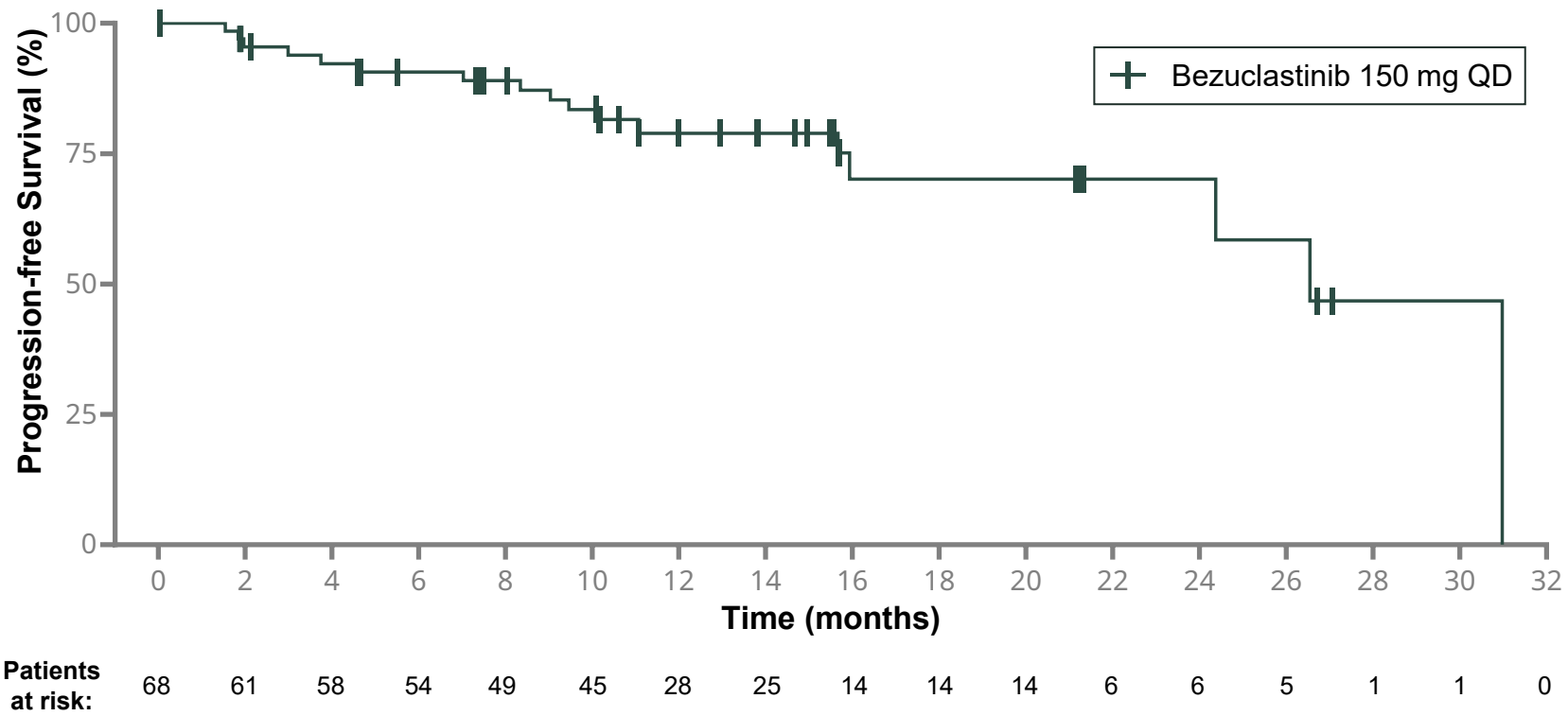
Data cutoff: March 31, 2026. Median (range) treatment duration: 63.0 (1.0–135.3) weeks.

[a]Droplet digital PCR limit of detection=0.03%.

AdvSM, advanced SM; ASM, aggressive SM; MC, mast cell; MCL, mast cell leukemia; PB, peripheral blood; SM, systemic mastocytosis; SM-AHN, SM with associated hematologic neoplasm; QD, once daily; VAF, variant allele frequency.

Bezuclastinib Demonstrated Early Evidence of Durable Responses and Prolonged PFS in Patients with AdvSM

PFS[a] per mIWG-MRT-ECNM criteria (n=68)



PFS and OS

- 12-month PFS rate: **79%** (95% CI: 65.5, 87.6)
- 12-month OS rate: **87%** (95% CI: 77.8, 93.0)

Event rates for PFS and OS were low at time of data cutoff, indicating that these endpoints are immature at a median follow up of 62 weeks

Disease Progressions

- Progression of AHN (n=8)
- Progression to AML (n=3)
- Progression of SM (n=2)
- Progression to MCL (n=1)

Data cutoff: March 31, 2026.

[a]PFS progression includes death or Central Response Review Committee assessment of progressive disease.

AdvSM, advanced SM; AHN, associated hematologic neoplasm; AML, acute myeloid leukemia; CI, confidence interval; MCL, mast cell leukemia; mIWG-MRT-ECNM, modified International Working Group–Myeloproliferative Neoplasms Research and Treatment–European Competence Network on Mastocytosis; OS, overall survival; PFS, progression-free survival; QD, once daily; SM, systemic mastocytosis.

Bezuclastinib Demonstrated a Favorable Safety Profile in AdvSM

	Bezuclastinib 150 mg QD (N=81)	
Treatment-related AEs (TRAEs), n (%)	75 (93)	
Treatment-related SAEs, n (%)	6 (7)	
Dose reductions due to TRAEs, n (%)	13 (16)	
Discontinuations due to TRAEs, n (%)	1 (1)	
TRAEs in ≥10% of patients, n (%)	**Any grade**	**Grade ≥3**
Hematological events		
Neutropenia[a]	25 (31)	19 (24)
Thrombocytopenia[a]	20 (25)	11 (14)
Anemia	13 (16)	8 (10)
Non-Hematological events		
Hair color changes	25 (31)	0
Altered taste[a]	23 (28)	0
ALT/AST increased[a]	17 (21)	2 (3)
ALP increased	11 (14)	4 (5)
Diarrhea	13 (16)	1 (1)
Nausea	12 (15)	2 (3)
Alopecia	9 (11)	0
Peripheral edema	9 (11)	0

- Median (range) duration of exposure: 63.0 (1.0–135.3) weeks
  - Majority of patients remained on their starting dose of bezuclastinib
- Dose reductions were primarily due to hematological events
- Hematological events were reversible and manageable
- Treatment-related hepatic events were transient and manageable lab abnormalities
  - No treatment-related Grade 4 hepatic AEs
  - Of 2 patients who experienced treatment-related AEs of Grade 3 ALT/AST increase, 1 discontinued treatment and 1 remains on study following dose reduction
- No treatment-related deaths were reported

Data cutoff: March 31, 2026. [a]Pooled terms.

AdvSM, advanced systemic mastocytosis; AE, adverse event; ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; QD, once daily; SAE, serious AE; TRAE, treatment-related AE.

Bezuclastinib Represents a Promising New Treatment Option for ASM Patients

Patients receiving bezuclastinib achieved **high rates of response**:

- 65% ORR per mIWG-MRT-ECNM
- 81% ORR (CR+CRh+PR) per PPR

Significant reductions in objective disease markers underscore potent target engagement and impact on KIT-driven disease pathology:

- Serum tryptase: ↓ ≥50% in 89% of patients
- Bone marrow mast cell burden: ↓ ≥50% in 89% of patients
- KIT p.D816V variant allele frequency: ↓ ≥50% in 91% of patients



Bezuclastinib was well-tolerated, with infrequent need for dose reduction and no patients requiring discontinuation for treatment related adverse events

- Encouraging safety profile potentially allows for concomitant treatment in patients who require other cytoreductive therapies for AHN or post-transplant

AdvSM PDUFA target action date set for June 29, 2027

Significant Market Opportunity in Systemic Mastocytosis With Bezuclastinib's Clinical Profile

Promising Growth Trends in SM Management

~40%
Growth in TKI Utilization in SM*

In Testing and Diagnostics

Patients Diagnosed

Limited Competition Creates Unmet Market Needs

$3.5B - NonAdvSM: AYVAKIT has suboptimal therapeutic dosing and is often used off label

$500M - AdvSM: AYVAKIT has significant safety concerns including risk of intracranial hemorrhage

Large Market Opportunity Across Major Markets

$4 Billion+ Global
Annual Market Opportunity

SUMMIT & APEX results together position bezuclastinib as potential best-in-class option for SM patients

*Internal Open and Closed Claims Analysis in SM

cogent BIOSCIENCES

Best-in-Class Research Pipeline



Cogent Pipeline Highlight: Pan-KRAS Inhibitor

Potency

Best-in-class across prevalent KRAS mutations

Selectivity

No inhibition of H/NRAS for potential improvement in tolerability vs. multi-RAS inhibitors

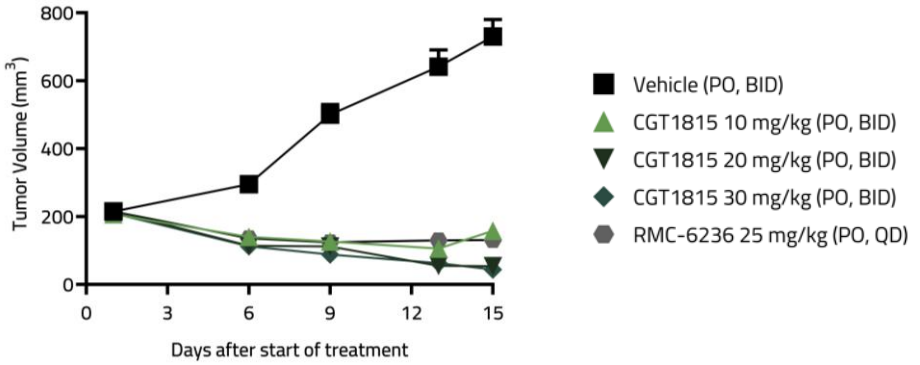
Drugability

Pro drug provides QD / low dose option for patients with excellent ability to combine

Cell Line	Tumor Type	KRAS Mutation	CGT1263 Cellular IC_{50}	RMC-6236 Cellular IC_{50}
MKN1	Gastric Cancer	Wild Type Amplified	0.65 nM	8.5 nM
NCI-H2009	Non-small cell lung cancer	G12A	0.11 nM	0.89 nM
NCI-H358	Non-small cell lung cancer	G12C	0.22 nM	0.30 nM
AsPC-1	Pancreatic cancer	G12D	0.24 nM	1.28 nM
A549	Non-small cell lung cancer	G12S	0.35 nM	0.65 nM
SW480	Colorectal cancer	G12V	0.37 nM	0.29 nM
HCT116	Colorectal cancer	G13D	1.0 nM	0.96 nM
NCI-H460	Non-small cell lung cancer	Q61H	0.30 nM	0.50 nM

- CGT1263 (the active form of CGT1815) showed pM/nM pERK inhibition across the spectrum of KRAS cell lines shown

$KRAS^{G12D}$ ASPC-1 tumors



Treatment	%TGI (Day 15)	Max %R
CGT1815 10 mg/kg (PO, BIDx14)	78	40 (D13)
CGT1815 20 mg/kg (PO, BIDx14)	93	75 (D13)
CGT1815 30 mg/kg (PO, BIDx14)	94	79 (D15)
RMC-6236 25 mg/kg (PO, QDx14)	82	39 (D15)

- CGT1815 showed superior tumor growth inhibition (>90%) at the 20 and 30 mg/kg BID PO dose levels compared to RMC-6236

Cogent Pipeline Highlight: JAK2 V617F Inhibitor

Selectivity

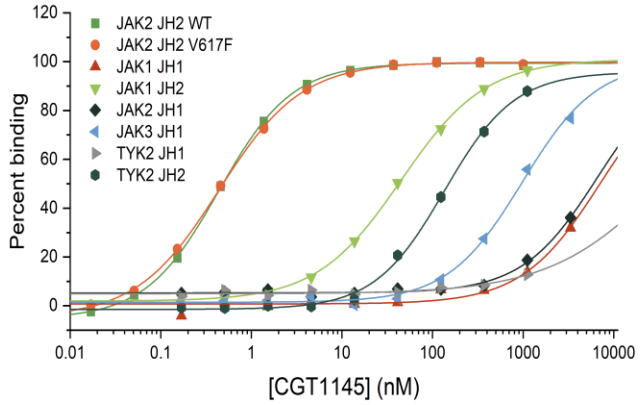
100+ fold selectivity in both binding and cellular assays for JAK2 V617F over JAK2 WT

↑ molecular response vs SOC agents
↓ thrombosis risk, ↓fibrotic risk, and ↓inflammation

Drugability

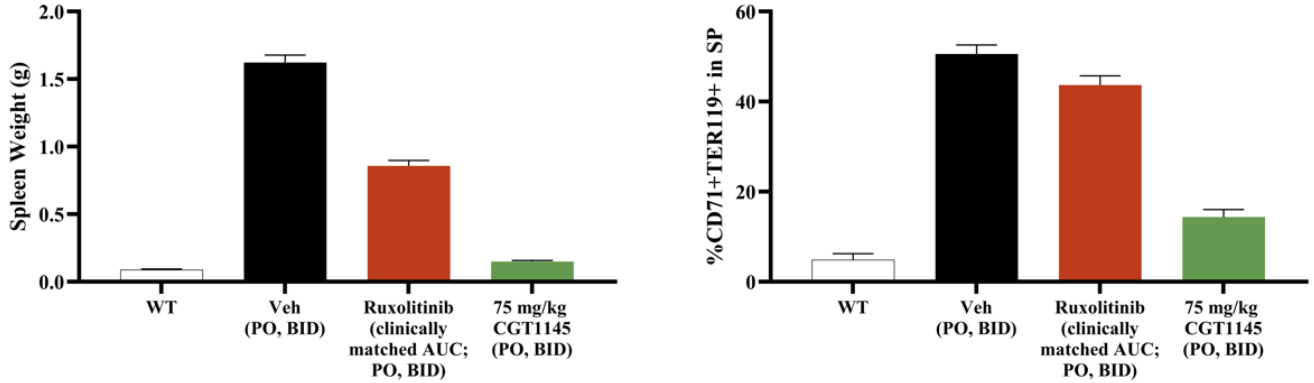
QD dose option for patients with excellent ability to combine

CGT1145 is Selective for the JAK2 JH2 Domain



CGT1145 binds to the JAK2 JH2 domain with sub-nM potency and is over 100x selective vs JAK1 JH2, JAK1/2/3 JH1, and TYK2 enzymes

Spleen Outcomes

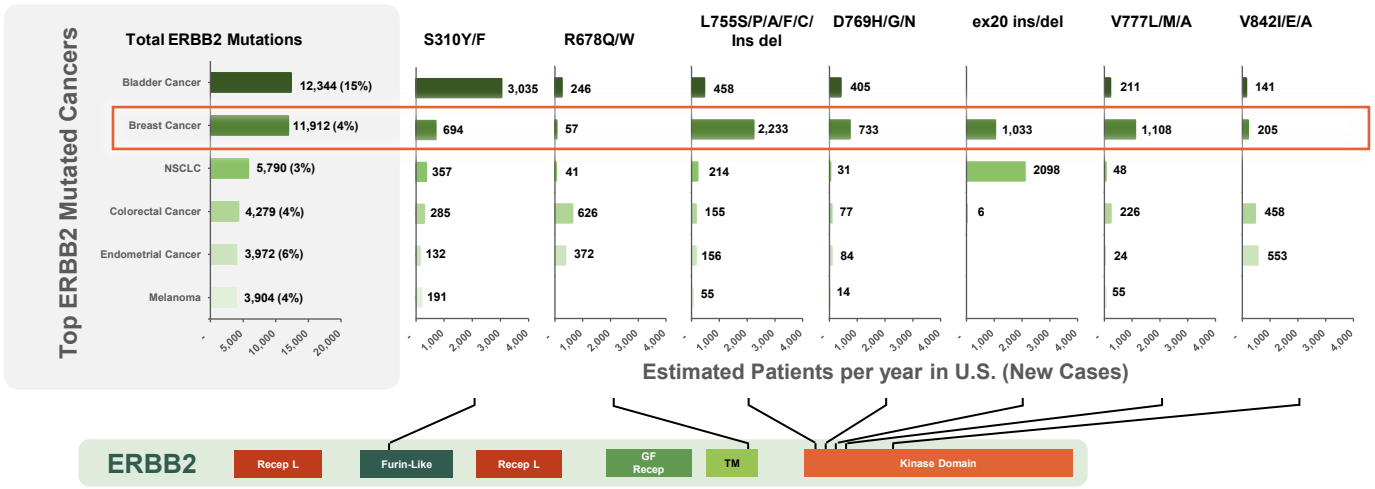


Treatment with CGT1145 led to normalization of spleen weight and decreased CD71+TER119+ erythroid precursor accumulation in the spleen, supporting the potential of CGT1145 as a disease-modifying therapy through restoration of bone marrow function and attenuation of extramedullary hematopoiesis

Creating a Best-in-Class CNS-penetrant, pan-mutant ErbB2 Inhibitor

CGT4255 is a highly potent and selective ErbB2 inhibitor targeting resistance (YVMA), kinase, and extracellular domain mutations, with best-in-class potential performance in multiple underserved patient populations

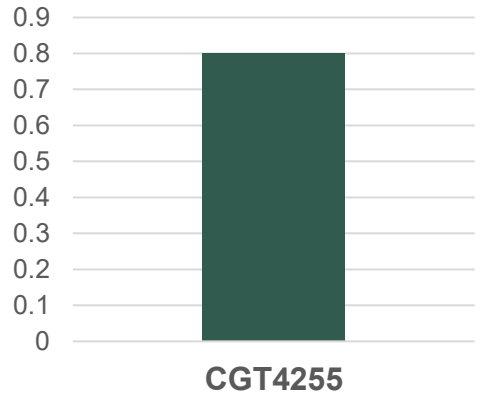
Prevalence of Oncogenic Mutations of ErbB24,5



ErbB2 Cellular IC_{50} Inhibition of pErbB2					
	ErbB2 WT	L755S	YVMA	S310F	V842I
CGT4255	8 nM	9 nM	3 nM	7 nM	15 nM

Adjusted for FBS-binding

Brain Penetrance (Kpuu)

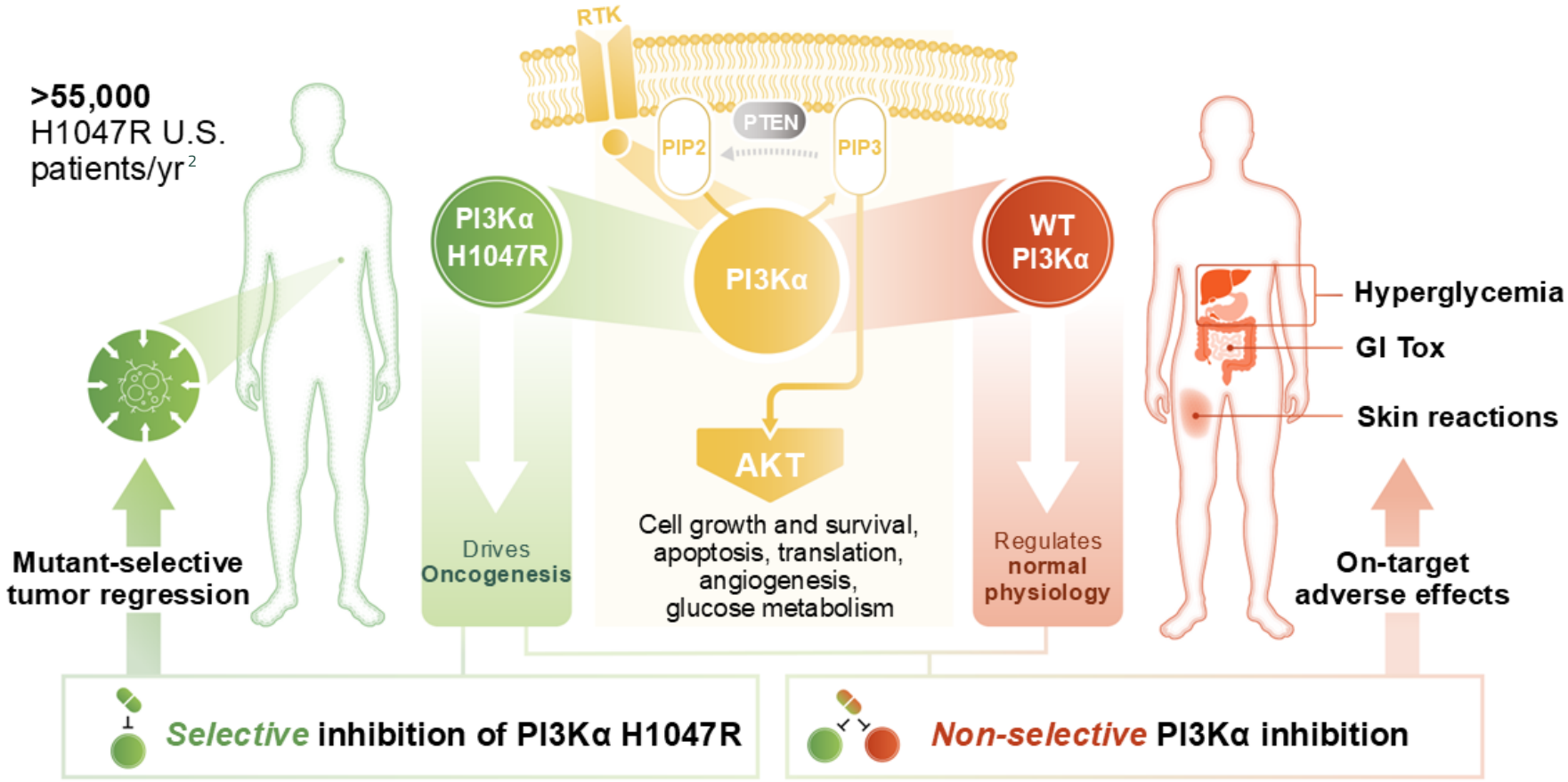


Observed Kpuu when dosed at 100 mg/kg; 1h time point in mice

Outperform:

- Minimal shift across all relevant mutations, YVMA and ErbB2 wt isoforms
- Best in class potential CNS exposure
- Superior whole blood stability across ErbB2-covalent MOA/drug class
- Superior *in vitro and in vivo* performance vs. SOC- ex.~Tucatinib
- Ability to combine therapeutically with ADC, other TKIs and mAbs

Selective pan-mutant PI3Kα Inhibition Avoids PI3Kα Wild Type Toxicity for Improved Efficacy and Tolerability



- On-target inhibition of wild type PI3Kα by approved inhibitors leads to tolerability issues including hyperglycemia, hyperinsulinemia, gastrointestinal issues, and skin reactions[1]
- Increases in insulin result in activation of PI3Kα in tumor cells and diminished efficacy[1]
- A mutant selective inhibitor will avoid these toxicities resulting in better tolerability, greater target coverage, and improved efficacy compared to approved agents

1. Hanker, A. B.; Kaklamani, V.; Arteaga, C. L. Challenges for the Clinical Development of PI3K Inhibitors: Strategies to Improve Their Impact in Solid Tumors. Cancer Discov. 2019; 9: 482–491

2. The AACR Project GENIE Consortium. AACR Project GENIE: Powering Precision Medicine Through An International Consortium. Cancer Discov. 2017; 7: 818–831.

Cogent Biosciences: Major Catalysts Expected in 2026

Bezuclastinib

- Gain approval and successfully launch in GIST & NonAdvSM
- ✓ Complete GIST NDA submission (11/30/26 PDUFA)
- ✓ Submit NonAdvSM NDA (12/30/26 PDUFA)
- ✓ Present detailed GIST data at ASCO, May 30, 2026
- ✓ Present detailed AdvSM data at EHA, June 13, 2026

Pipeline

- Submit IND for CGT1815; novel, selective pan-KRAS inhibitor
- Submit IND for CGT1145; novel, selective JAK2 V617F inhibitor
- ✓ Initiate dose escalation for CGT4255, CNS-penetrant ErbB2 inhibitor
- ✓ Initiate dose escalation for CGT6297, novel, selective PI3Kα inhibitor

Corporate

- ✓ Build highly capable US commercial team to support bezuclastinib launch
- Identify ex-US commercial partner(s) for bezuclastinib, including European go-to-market strategy

$866M pro forma Q2 2026 cash balance sufficient to fund operations into late 2028


cogent
BIOSCIENCES
Real Challenges.
Real Solutions.
Cogentbio.com