

U.S. FDA Approval of EKITNA™ (bezuclastinib)

November 24, 2026

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Outside the United States, bezuclastinib is investigational and has not been approved by any regulatory authority.

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Opening Remarks
Andrew Robbins, CEO

Speakers and Agenda



Andrew Robbins
President &
Chief Executive Officer



Jessica Sachs, MD
Chief Medical Officer



Cole Pinnow
Chief Commercial Officer

• Opening Remarks	Andrew Robbins, CEO
• EKITNA Clinical Results	Dr. Jessica Sachs, CMO
• Launch Overview	Cole Pinnow, CCO
• Closing Remarks	Andrew Robbins, CEO
• Q&A	All

EKITNA – Now Approved for GIST Patients!

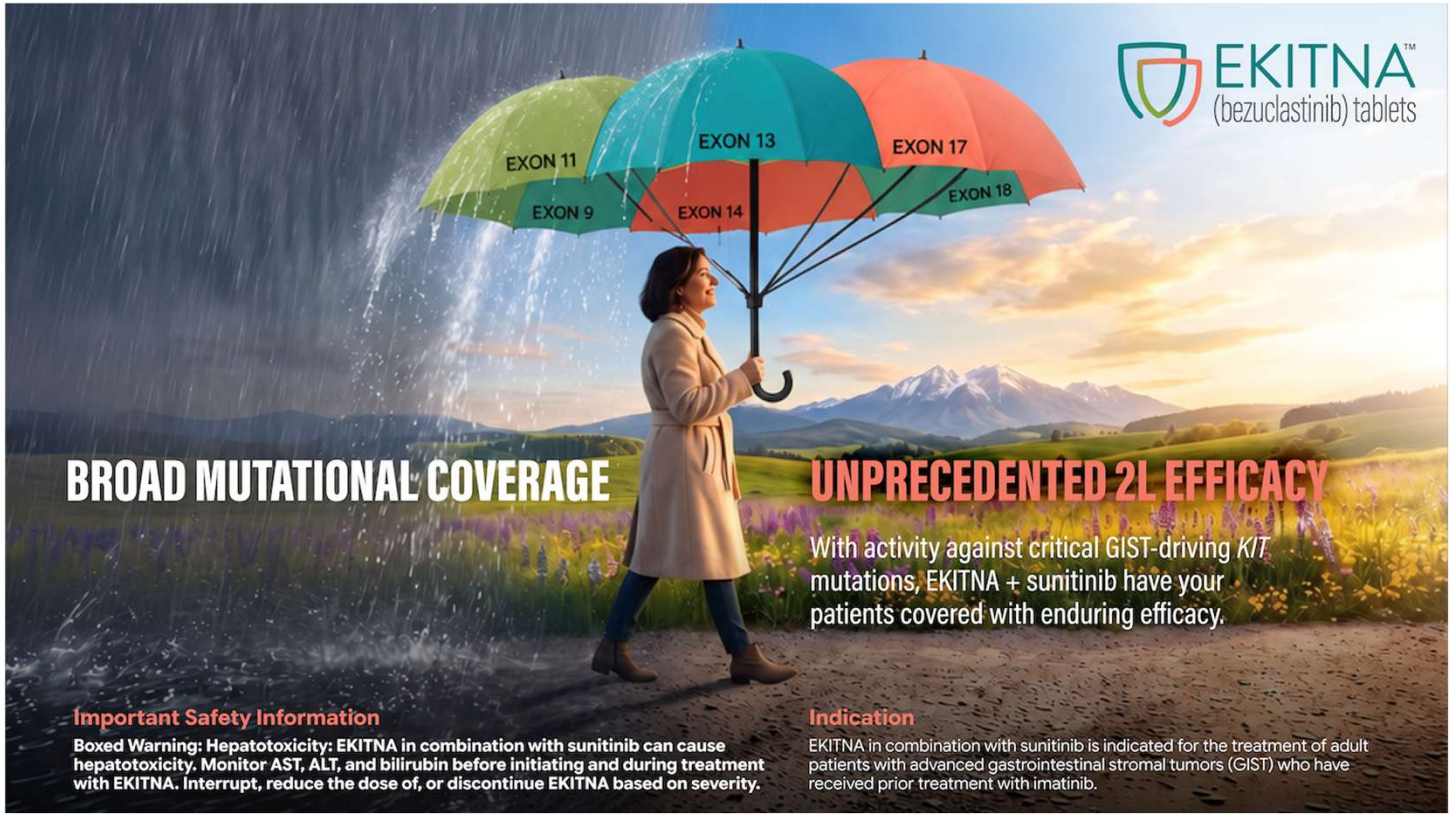
EKITNA™
(bezuclastinib) tablets



A kinase inhibitor indicated in combination with sunitinib for the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with imatinib.

- **First new treatment for 2nd-line GIST patients in over 20 years**
- **Only FDA approved treatment for GIST patients to show an advantage over an existing standard of care in pivotal trial**

EKITNA Combination Provides New Hope for GIST Patients



EKITNA U.S. Label: Highlights of Prescribing Information

Indications and Usage	EKITNA is a kinase inhibitor indicated in combination with sunitinib for the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with imatinib.
Dosage and Administration	The recommended dosage of EKITNA is 600 mg orally once daily, in combination with sunitinib.
Warnings and Precautions	Hepatotoxicity (Boxed Warning) and Embryo-Fetal Toxicity
Adverse Reactions	Most common adverse reactions, (≥20%): diarrhea, increased liver transaminases, hypertension, dysgeusia, nausea, hair color changes, fatigue, abdominal pain, vomiting, decreased appetite, stomatitis, GERD, rash, dyspepsia, and pyrexia.



EKITNA U.S. Prescribing Information. This summary does not include all information needed to use EKITNA safely and effectively. Please see full Prescribing Information.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Unmet Need for GIST Patients
Andrew Robbins, CEO

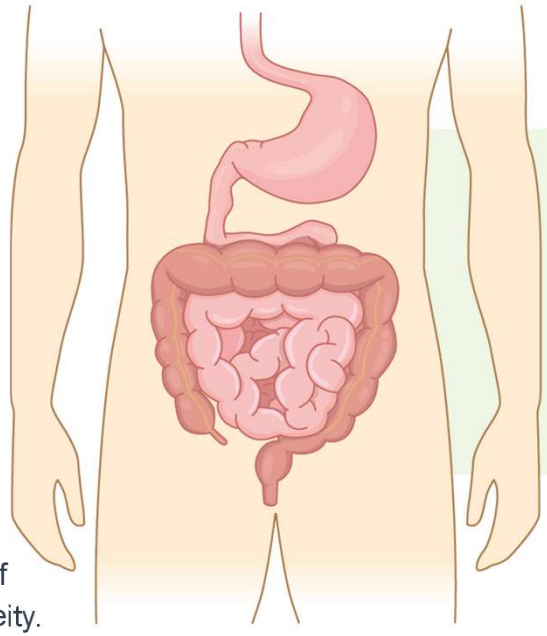
Gastrointestinal Stromal Tumors (GIST) Overview

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]

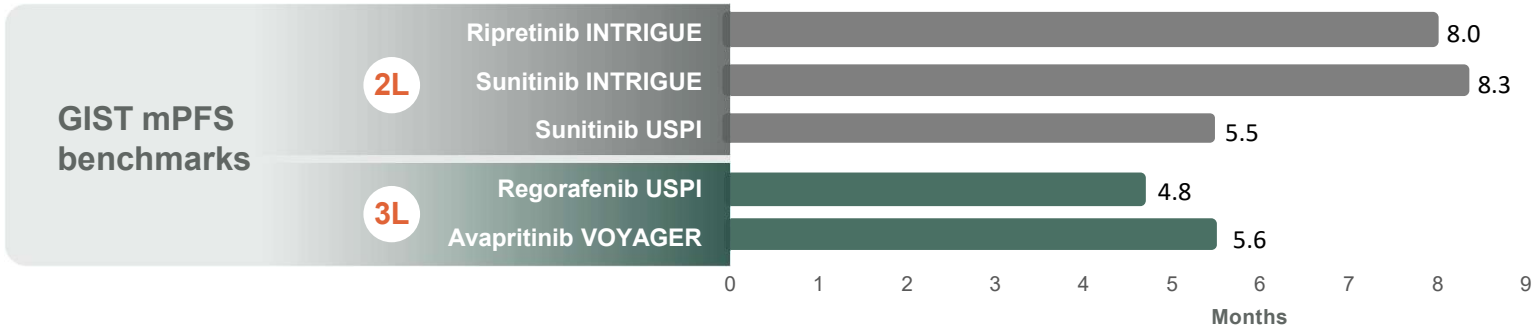
Diarrhea, Nausea, Vomiting, Abdominal pain, Bloating, Gastroesophageal reflux disease, GI bleeding, Loss of appetite,
Weight loss

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



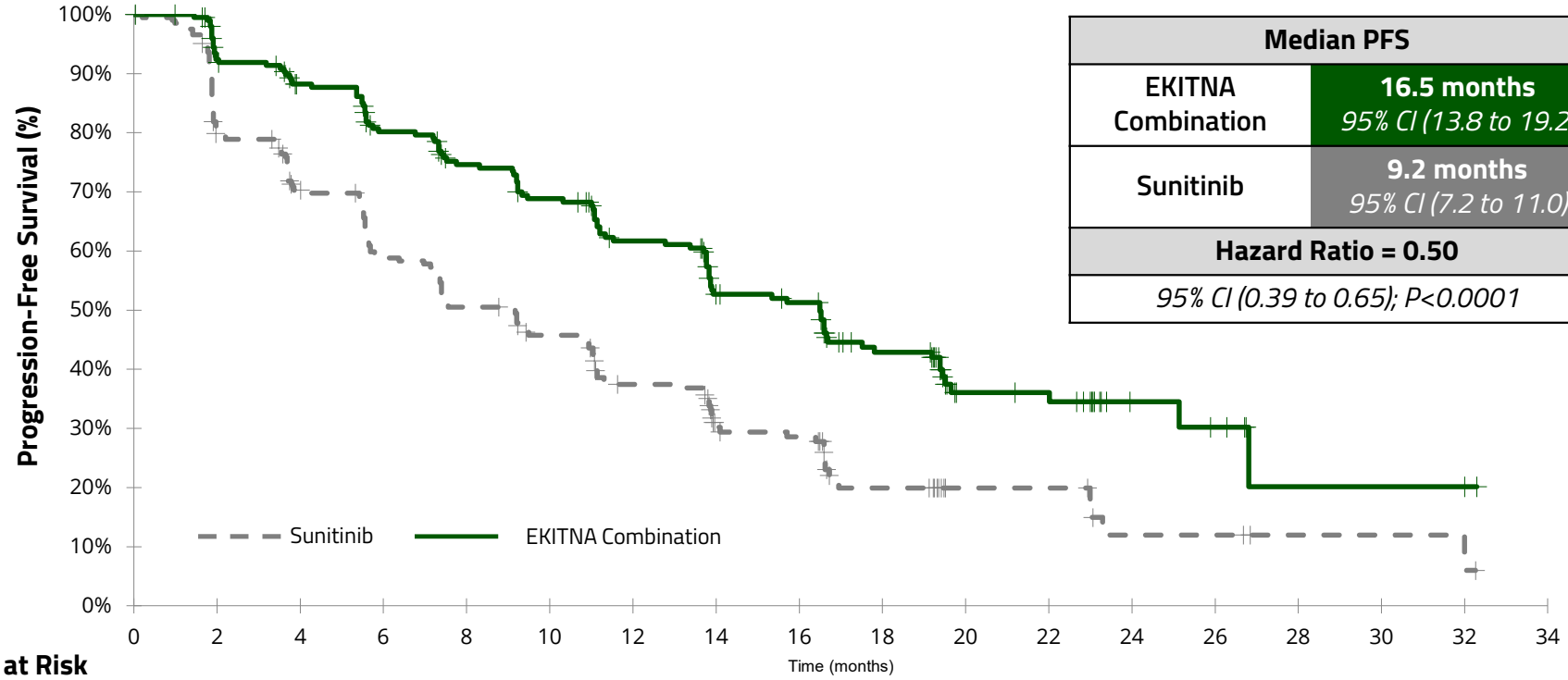
ORR/PFS for all approved agents was obtained from labeled information from those agents



EKITNA Clinical Results

Dr. Jessica Sachs, CMO

PEAK Trial: EKITNA Combination Extended PFS With 50% Reduction in Risk of Progression or Death



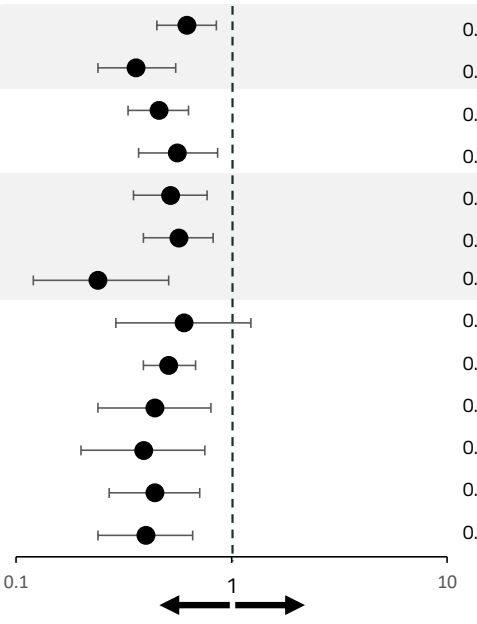
Median PFS	
EKITNA Combination	**16.5 months** *95% CI (13.8 to 19.2)*
Sunitinib	**9.2 months** *95% CI (7.2 to 11.0)*
Hazard Ratio = 0.50	
95% CI (0.39 to 0.65); P<0.0001	

Patients at Risk

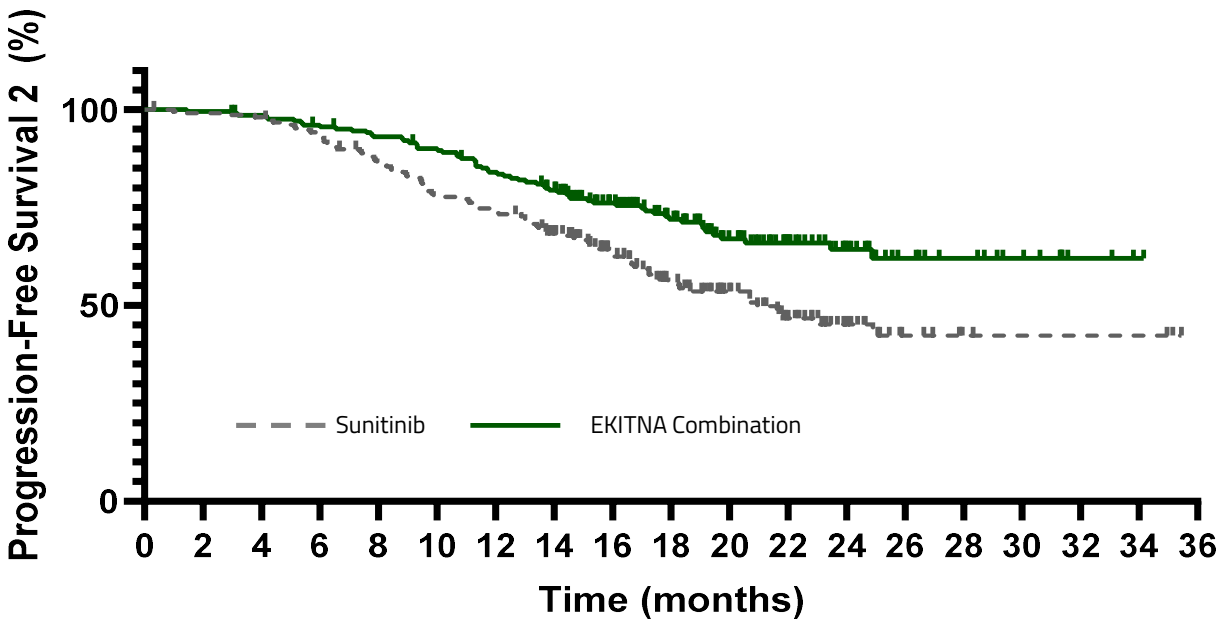
EKITNA Combination	204	180	166	146	130	119	102	76	72	51	24	23	8	6	2	2	2	0
Sunitinib	209	161	137	113	97	85	64	39	35	19	9	9	4	4	2	2	2	0

PEAK Trial: EKITNA Combination Demonstrated Impressive PFS Benefit Across Subgroups

	Subgroup	EKITNA Combination	Sunitinib	Hazard Ratio (95% CI)	Median, mos	
		Patients with primary outcomes, n/N (%)		EKITNA Combo vs Sun	EKITNA Combo	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



PEAK Trial: ORR and PFS2 Results Supports the EKITNA Combination Durability of Response



Patients at Risk

EKITNA Combination	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	
EKITNA Combination	**Not yet reached**
Sunitinib	**21.0 months**
Hazard Ratio = 0.57	

Objective Response, % (95% CI)	
EKITNA Combination N=204	**45.6** (38.6-52.7)
Sunitinib N=209	**25.8** (20.0-32.3)
P value<0.0001	

- 6.4% of patients achieved a **Complete Response** on EKITNA combination

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

Safety Overview from EKITNA Prescribing Information & PEAK trial

- **Most common adverse reactions (≥20%**): diarrhea, increased liver transaminases, hypertension, dysgeusia, nausea, hair color changes, fatigue, abdominal pain, vomiting, decreased appetite, stomatitis, GERD, rash, dyspepsia, and pyrexia

Higher frequency vs. sunitinib mono	Lower frequency vs. sunitinib mono
• *Increased liver transaminases* • *Hair color changes* • *Dysgeusia*	• *PPE* • *Stomatitis* • *Thrombocytopenia*

- **Serious adverse reactions (≥2%):** anemia, ALT increase, pneumonia and hemorrhage
- **Risk of Hepatotoxicity (Boxed Warning)** consisting of reversible transaminase elevations was manageable with monitoring and dose modification
  - Consistent time to onset with 93% of events occurring within first 4 months
  - Dose interruption (13%), dose reduction (9%) and discontinuation occurred in only 1% of patients
  - All events fully resolved following discontinuation; no patient experienced serious hepatic outcomes



EKITNA Launch Overview

Cole Pinnow, CCO

Cogent Field Team Prepared for EKITNA Launch

EKITNA™ (bezuclastinib) tablets

Brand Strategy

Drive Continued Awareness

Scale awareness of PEAK data among HCPs and Patients

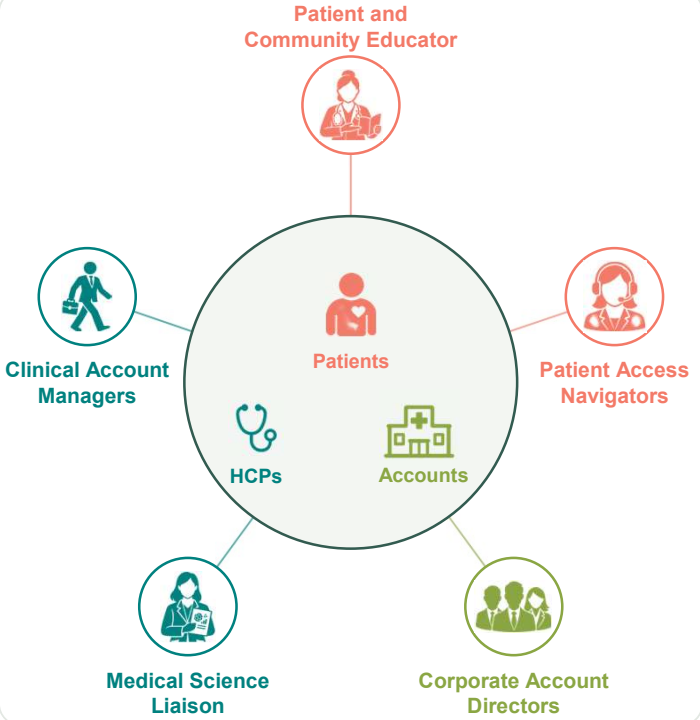
Establish as Standard of Care

EKITNA + sunitinib to be the new Standard of Care following imatinib resistance or intolerance

Excellent Access & Relationships

Drive adoption and sustained use by maximizing access and providing best-in-class support for both patients and HCPs

Cogent's Cross Functional Customer Facing Team



Engagement to Date

100% **Outreach with Key GPOs and Community Oncology Networks**
Favorable feedback on PEAK data and contract structure

>96% **Top 40% of Accounts Profiled**
Includes HCPs who are high prescribers of sunitinib

>70% **PEAK Awareness**
Doubled among GIST HCPs this year*

*Source: Cogent Primary Market Research Jan to Oct 20, 2026

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Cogent Connect: Designed to Provide Best-in-Class Access for Patients

cogent connect™

Eligible commercially insured patients may pay as little as

$0

Copay assistance

Copay, coinsurance and deductible assistance, up to $15,000 per year

Patient Assistance

No cost for eligible patients with little to no coverage or who are ineligible for copay assistance

Fast Start

Free supply for 30+ days while securing coverage

Bridge Program

30+ days of free supply for eligible insured patients with temporary coverage gap

Sunitinib support

Sunitinib provided for eligible GIST patients in Fast Start, Patient Assistance and Bridge programs

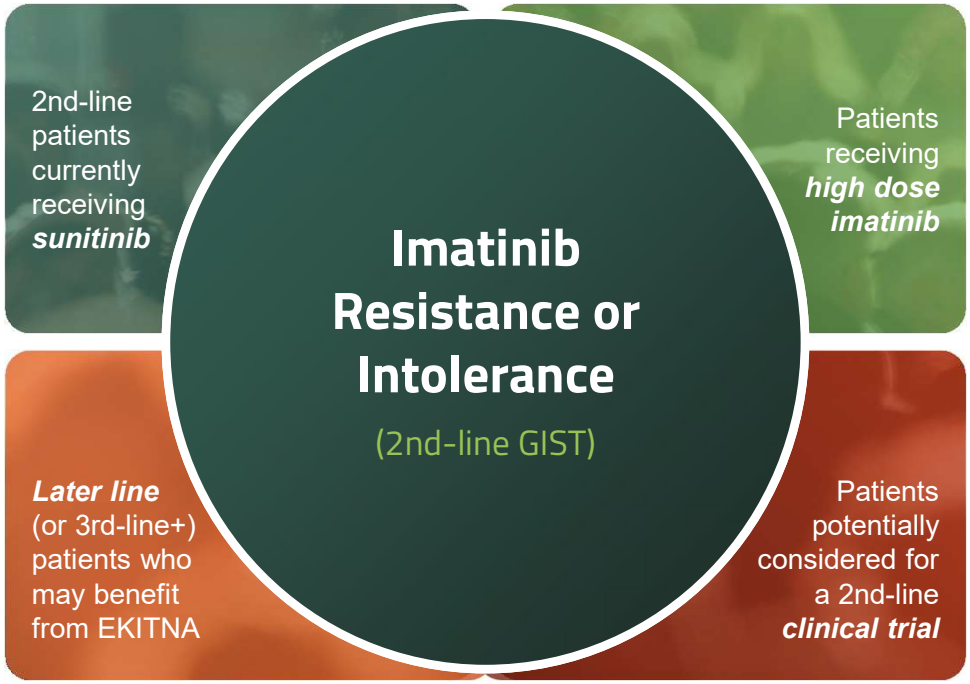
Eligibility renewal

Copay: annual reverification. Patient Assistance: Medicare each January; commercial monthly, up to 12 months

Additional terms and conditions apply to all affordability programs

EKITNA Launch Underway with Key Areas of Focus

Segmentation of Eligible Market
>3,000 patients annually



Launch Priorities

1. EAP transition
2. Pathway inclusion
3. Rapid payer coverage
4. Target key stakeholders
5. Rapid scientific dissemination & education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Closing Remarks
Andrew Robbins, CEO


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Q&A
Real Challenges.
Real Solutions.
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