

Expanded Access Program for gallium maltolate (GaM) Now Open

Investigational cancer treatment with the potential to slow brain tumor growth is now available for patients with relapsed/refractory glioblastoma.

OAKLAND, CALIFORNIA, UNITED STATES, July 3, 2024 / EINPresswire.com/ -- xCures, a healthcare data platform provider, announced that the US Food and Drug Administration (FDA) has approved an Expanded Access Program (EAP) for gallium maltolate (GaM), a new cancer therapy.



Sponsored by Imaging Biometrics, this program was set up specifically for patients with relapsed/refractory histologic or molecular glioblastoma, who have no other standard treatment

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options available.

The EAP is open to physicians whose patients have exhausted standard-of-care therapies, fit the eligibility criteria, and cannot access the open-enrolling phase I clinical trial for the investigation of GaM.

"This Expanded Access program will help bring GaM to patients in need while carefully monitoring patients and gathering data that will inform and improve future cancer

therapies," said Mika Newton, CEO of xCures. "Our commitment at xCures is to bridge the gap between clinical trials and patient care by harnessing the power of Real-World Evidence, which is a key step this initiative will help drive forward."

"The opening of this EAP marks a significant milestone in our mission to combat glioblastoma," said Michael Schmainda, president and CEO of Imaging Biometrics. "With gallium maltolate now available through the Expanded Access program, we can provide a new therapeutic option to patients who have exhausted all other avenues, offering hope and potentially extending life. Our dedication remains to advancing research and delivering solutions that can make a real difference in the fight against cancer."

Physicians and patients can find more information about this program (NCT06404034) and how to request access at <u>www.xcures.com/gam</u>.

About gallium maltolate (GaM):

GaM is a novel gallium formulation that differs from gallium nitrate, a first-generation FDAapproved gallium compound that has been extensively studied in preclinical and clinical studies. The difference between GaM and gallium nitrate is that GaM has greater anti-tumor activity than Ga nitrate and can be taken orally rather than through iv administration. GaM has demonstrated promising early efficacy for patients with various malignancies.

About Expanded Access:

Expanded access is the treatment use of an unapproved drug under special forms of investigational new drug applications (IND) outside of a clinical trial by people with serious or life-threatening conditions who do not meet the enrollment criteria for the clinical trial in progress.

About the Program:

This Expanded Access program is intended to provide GaM for compassionate use in glioblastoma patients who have exhausted available therapies. The program aims to collect sufficient information about the patient's treatment to provide a complete and accurate case report to health authorities including patients' response and duration of response using real-world data, analysis of imaging results, an assessment of GaM safety and tolerability, and the effect of GaM treatment on patient/caregiver reported functional status and quality-of-life.

About xCures:

Launched in 2018, xCures Inc. operates an AI-assisted platform that automatically retrieves and aggregates medical records from any US care site. Data is extracted and structured within 15 minutes to offer a sophisticated view of a patient's fully longitudinal health journey that encompasses everything from genomics to social determinants of health.

Through a variety of tools and data products, xCures provides clinically actionable, real-time insights that facilitate patients care. For more information, contact info@xcures.com or visit http://www.xcures.com.

About Imaging Biometrics:

Imaging Biometrics is a wholly owned subsidiary of IQ-AI Limited, (LON: IQAI), and focuses on delivering quantitative imaging platforms and therapeutics that transform how clinicians diagnose and treat patients more efficiently and effectively. For more information about Imaging Biometrics, visit the company's website at <u>www.imagingbiometrics.com</u>. Follow IB on Twitter, @IQAI_IB.

Patrick van der Valk xCures Inc pvandervalk@xcures.com Visit us on social media: Facebook X LinkedIn Instagram YouTube TikTok Other

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