REGLAGENE RECEIVES FDA ORPHAN DRUG DESIGNATION FOR INNOVATIVE BRAIN CANCER TREATMENT

New therapy crosses blood-brain barrier to give new hope to patients with rare, aggressive cancer

TUCSON, ARIZONA, UNITED STATES, January 4, 2024 /EINPresswire.com/ -- Reglagene, Inc., has received an exclusive orphan drug designation (ODD) from the US Food and Drug Administration (FDA) for its innovative, orally administered treatment for glioblastoma, a rare and particularly aggressive form of brain cancer with very poor prognosis for survival. The firm's therapy, RGN6024, is on track to give new hope to patients in a field where median brain cancer survivals post diagnosis are barely over a year.

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> *Reglagene CEO Richard Austin, Ph.D., MBA*

"The key obstacle to solving this challenge has historically been crossing the blood-brain barrier (BBB), a natural filter we all have that prevents toxins and medicines from entering the brain," said Reglagene Chief Executive Officer Richard Austin, Ph.D., MBA, adding "Only 2% of all marketed drugs cross the BBB. Our therapy has this capability and attacks cancer. Many therapies and drug-delivery systems have tried and failed to access cancer in the brain. Reglagene has found a way to make this possible with our brain-penetrant therapy RGN6024."

The focus of Reglagene's research is in developing therapies that work by disrupting the function of the tubulin protein. Tubulin polymerizes into long filaments. These filaments play a crucial role in a cell's support and movement of materials among its different parts. Therapies that disrupt tubulin function cause cancer cells to die.

While tubulin-disrupting therapies have successfully treated breast, lung, ovarian, thyroid, and prostate cancers, their use to treat malignant brain tumors has evaded researchers because of

an inability to navigate the blood-brain barrier.

A guiding principle for the Reglagene team is to develop orally administered, well-tolerated medicines for patients to use in the comfort of their own homes. RGN6024 fits these criteria. Most cancer medicines are given intravenously in clinical settings and cause many unwanted side effects.

The FDA's orphan drug designation program provides incentives to organizations for the development of innovative treatments for rare diseases. To qualify for an ODD, Reglagene had to show the potential of RGN6024 for treating glioblastoma, a rare form of brain cancer affecting fewer than 200,000 individuals in the United States. With the ODD granted, Reglagene is eligible for benefits such as tax credits for human clinical trials or qualified clinical testing costs, a waiver of the Prescription Drug User Fee Act application fee when a marketing application is submitted, and the potential to receive 7 years of marketing exclusivity upon product approval.

In addition to glioblastoma, Reglagene believes RGN6024 will also be useful for treating breast, lung, and melanoma cancer patients experiencing metastatic brain cancer. Reglagene also has multiple, orally administered, blood-brain barrier penetrant tubulin-targeting agents that are being studied for the treatment of neuro-inflammatory diseases as well as age-related macular degeneration and diabetic retinopathy.

About Reglagene, Inc.
Named as a recipient of a 2023 AZ BIO Fast Lane Award, Reglagene, Inc. is a ground-breaking therapeutics company designing small-molecule treatments to pass through the blood-brain barrier. With brain cancer survival rates at barely a year using current treatment methods, Reglagene's new medicine and others in its portfolio are poised to revolutionize the care of high-grade gliomas, metastatic brain cancers and neurological disorders. The firm's core expertise lies in the design and development of brain-penetrant medicines, allowing them to confront these diseases head-on. The company recently closed a non-brokered private placement of convertible preferred stock, which was oversubscribed and resulted in aggregate gross proceeds to the company of $5.4 million. Connect with Reglagene at www.reglagene.com and follow the company on LinkedIn at https://www.linkedin.com/company/reglagene/.

Forward-Looking Statements
Certain statements in this press release that are not statements of historical or current fact may constitute "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward looking statements involve known and unknown risks, uncertainties, and other factors that could cause the actual results of Reglagene (the "Company") to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. The forward-looking statements in this press release, including statements regarding the Company's anticipated use of proceeds from the private placement, the potential effectiveness of the

Company’s therapeutic treatments for brain diseases, or the potential for FDA approval of the Company’s therapeutics are based upon the Company’s current expectations and involve assumptions that may never materialize or that may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions; (ii) regulatory requirements; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; and (v) actual costs associated with the Company’s clinical trials as compared to management's current expectations. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by applicable securities laws.

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