

FDA Grants Fast Track Designation to Aveta Biomics' Drug APG-157 for Neoadjuvant Treatment of Head and Neck Cancer

FDA Fast Track Designation of APG-157 Marks Key Step Toward Potential Accelerated Approval in Head & Neck Cancer Treatment



BOSTON, MASSACHUSETTS, UNITED STATES, August 22, 2024 /EINPresswire.com/ -- Aveta Biomics, a pioneering oncology company developing first-in-class oral immuno-oncology drugs, is pleased to announce that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to APG-157, its next-generation immuno-oncology drug, for the neoadjuvant treatment of [Head and Neck Cancer](#) (HNC). This designation underscores the potential of APG-157 to address a significant unmet medical need in treating a highly challenging form of cancer.

The FDA's Fast Track Designation is intended to facilitate the development and to expedite the review of drugs aimed at treating serious conditions with unmet medical needs. This designation allows for more frequent interactions with the FDA, eligibility for rolling submissions for a marketing application, and potential Accelerated Approval, ultimately aiming to bring promising new treatments to patients more rapidly.

"There is an urgent need for new treatments for head and neck cancer patients, many of whom face poor survival odds and considerable morbidities following current standard-of-care treatments, including surgery, radiotherapy, and chemotherapy/targeted treatments. The rare grant of Fast Track Designation for neoadjuvant treatment in Head and Neck Cancer underscores the FDA's recognition of the potential role of APG-157 in providing meaningful treatment benefits to these patients," said Parag Mehta, PhD, Chief Executive Officer of Aveta Biomics.

Head and Neck Cancer affects approximately 900,000 people globally, with an overall five-year mortality rate of around 50%, a figure that has remained largely unchanged for decades. The molecular complexity of these tumors presents significant challenges for existing treatments, including targeted therapies. APG-157 is a first-in-class drug that acts through a dual mechanism: inducing selective apoptosis of cancer cells while also reprogramming the immune environment.

"This Fast Track Designation, based on our comprehensive Phase 1 and Phase 2 data, accelerates

our ability to bring our promising first-line therapy to all newly diagnosed, locally advanced Head and Neck Cancer patients in a frontline setting,” added Karim Malek, MD, MTh, MBA, Chief Medical Officer of Aveta Biomics.

About Aveta Biomics:

Aveta Biomics is an oncology company committed to developing next-generation of safer and highly effective cancer drugs based on mimicking the functions of body’s endogenous metabolites and processes. Aveta’s drugs stimulate the immune system to destroy cancer cells while sparing healthy cells. Aveta is conducting multiple clinical trials for head and neck cancer, high-grade adult glioma including [Glioblastoma](#), and pre-clinical studies for pediatric glioma. For more information visit <https://avetabiomics.com/>

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements, including those regarding the impact of the Fast Track Designation, the progress of our clinical trials, potential regulatory approvals, the development and commercial success of our drug candidates, and our strategic goals, reflect our current expectations and involve risks and uncertainties. Actual results may differ materially due to factors such as our ability to advance drug candidates through development and regulatory approval, clinical trial outcomes, competition, and economic conditions. Words like “may,” “will,” “could,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” and similar expressions are intended to identify forward-looking statements. These statements are based on current expectations and are subject to risks and uncertainties that could cause actual results to differ materially. We caution you not to place undue reliance on these statements, which speak only as of the date they are made. As a private company, we are under no obligation to publicly update or revise any forward-looking statements to reflect new information or future events, except as required by applicable law.

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