FDA Approves Phase II Clinical Trial for Ruxoprubart in ANCA Associated Vasculitis-a Chronic Rare Disease in Nephrology

-- The United States FDA Clears Initiation of Efficacy Trial in Anti-Neutrophil Cytoplasmic Antibody (ANCA)-Associated Vasculitis (AAV) Patients

CLEVELAND, OHIO, UNITED STATES, June 17, 2024 /EINPresswire.com/ -- NovelMed proudly announces the U.S. Food and Drug Administration's (FDA) clearance on Ruxoprubart, the investigational drug, for commencing an efficacy trial targeting patients with ANCA Associated Vasculitis (AAV), a rare autoimmune chronic ailment characterized by inflammation in small blood vessels. Currently, the standard of care (SOC) for AAV requires high doses of Glucocorticoids, along with prolonged administration of other immunosuppressive drugs. However, this approach comes with severe side effects, including general immune suppression and toxicity from glucocorticoids, leaving unmet needs in managing the disease's impact on vital organs and associated adverse events (AEs).

Results from Phase I and II trials of Ruxoprubart in PNH patients demonstrate the drug's selective blocking of the alternative pathway (AP) without affecting the classical pathway (CP), which is crucial for maintaining immunity. This selectivity presents a significant advantage over existing complement blockers approved by the FDA or under development, potentially eliminating the need for a Black Box Warning.

In a forthcoming twelve-patient AAV study, Ruxoprubart will be evaluated alongside the SOC, akin to the trial conducted for TAVNEOS®. TAVNEOS (avacopan) was approved by the FDA in 2022 for treating AAV. Ruxoprubart is anticipated to outperform TAVNEOS due to its comprehensive control over the pathway responsible for generating three major toxins contributing to the disease pathology: C3a, C5a, and MAC. While TAVNEOS only targets C5a, Ruxoprubart aims to neutralize two powerful toxins including C3a and C5a, offering a potentially superior treatment approach. "We are thrilled to have gained FDA approval to address AAV in patients with an inadequate response to standard of care. Through this study, we aim to compare Ruxoprubart with historical data on TAVNEOS, hoping to improve AAV patients' lives substantially" says Dr. Rekha Bansal, Chief Executive Officer of NovelMed.

Joseph Jankowski, Ph.D., VP, Business Development of NovelMed, expressed enthusiasm regarding the FDA's clearance, stating, "The FDA's clearance of the Phase II clinical trial for AAV marks a significant milestone for Ruxoprubart, which harbors potential as a versatile platform

for multiple indications." Ruxoprubart is positioned to compete with TAVNEOS with its potential for a superior safety and efficacy profile. Acquisition of TAVNEOS by Amgen for 3.7 Billion dollars underscores the value placed on treatments for AAV patients. Ruxoprubart is expected to be a next-generation product that can replace TAVNEOS.

Ruxoprubart's selectivity and specificity, based on the clinical data from ongoing trials, hold promise not only for AAV, but also for several other renal disorders, including aHUS, and IgAN. The drug's potential to offer a superior safety and efficacy profile sets it apart and places it in a strong position within the market. The alternative pathway (AP) plays a pivotal role in managing anemia, inflammation, and tissue damage in various complement-mediated disorders, including AAV.

NovelMed is committed to advancing the development of Ruxoprubart and addressing the unmet medical needs of patients with AAV and other complement-mediated disorders. The FDA's clearance of the Phase II trial represents a significant step forward in our mission to bring innovative and effective treatments to the market. We are actively exploring licensing, partnership, and acquisition opportunities to advance Ruxoprubart's development and approval across multiple rare disease indications. For further details, please visit www.NovelMed.com.

ABOUT ANCA ASSOCIATED VASCULITIS (AAV) −−−

Anti-Neutrophil Cytoplasmic Antibody-associated vasculitis (ANCA Vasculitis or AAV), is a rare autoimmune condition causing inflammation in blood vessels, often leading to swelling, narrowing, and sometimes blockage of blood vessels. It is characterized by the presence of Anti-Neutrophil Cytoplasmic Antibodies (ANCAs), targeting certain proteins within white blood cells, particularly neutrophils. It often causes a specific type of inflammation called crescentic glomerulonephritis, which can lead to kidney failure.
Diagnosis of AAV involves a comprehensive assessment of medical history, physical examination, specific laboratory tests, imaging studies, and sometimes tissue biopsies. The current treatment approach primarily focuses on immune system suppression to alleviate inflammation and prevent further organ damage, utilizing corticosteroids and immunosuppressants. Despite being a rare and complex disease, advancements in treatment strategies are a must for continued improvement in the outcome of AAV patients.
The prevalence of AAV in the United States is approximately 66,600 to 133,200 patients. TAVNEOS costs $75,051 annually per patient, with the potential to generate over 4 Billion in annual sales.

ABOUT RUXOPRUBART −−−

Ruxoprubart is a high affinity, humanized monoclonal antibody to Bb, selectively blocking the initiation and propagation of the alternative pathway (AP). By targeting the AP and sparing the CP pathway, Ruxoprubart holds promise for treating renal disorders, including ANCA vasculitis (AAV). Furthermore, Ruxoprubart shows therapeutic potential across a broad spectrum of rare

diseases and disorders, including but not limited to hematological (PNH), renal (aHUS, IgAN), neurological (NMOSD), and ocular (GA and Uveitis).
Recent commencement of Ruxoprubart proof-of-concept Phase II trial through intravenous (IV) administration in naïve PNH patients shows promising results with a clean safety and efficacy profile. The Subcutaneous (SC) route of administration is under regulatory review and is expected to start soon.

Clinical trials for Ruxoprubart can be found at www.clinicaltrials.gov, showing its potential to address various complement-mediated and associated illnesses where treatment options are inadequate or absent.

ABOUT NOVELMED ---

NovelMed is a clinical-stage biopharmaceutical company dedicated to developing antibody treatments for numerous complement-mediated disorders, particularly rare (orphan) diseases. We aim to innovate and develop novel biologics to address unmet needs in rare disease treatment. NovelMed boasts a robust portfolio of intellectual property with broad applications in rare and common diseases. This includes Ruxoprubart's potential to treat a range of complement-mediated disorders associated with uncontrolled AP activation. As part of its antibody platform, NovelMed also offers humanized antibodies to C3b and Factor P (Properdin), effectively targeting the AP. NovelMed actively seeks licensing, partnership, and acquisition opportunities to advance antibody development through Phase III and approval in multiple rare disease indications. For more information, please visit News (novelmed.com).

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