USAN Approves Generic Name “Ruxoprubart” for NM8074, an Antibody Therapy focused on Complement-Mediated Diseases

CLEVELAND, OH, UNITED STATES, January 8, 2024 /EINPresswire.com/ -- NovelMed, a clinical-stage biopharmaceutical company with expertise in inflammatory and complement-related diseases, is pleased to announce that the United States Adopted Name (USAN) Council has officially assigned the generic name "Ruxoprubart (Ruk”soe proo' bart)" to its monoclonal antibody candidate, NM8074, marking a significant milestone in the drug development process. Currently in Phase II trial for Paroxysmal Nocturnal Hemoglobinuria (PNH), a hemolytic disease, Ruxoprubart (NM8074) represents a significant breakthrough.

The USAN Council has approved the nonproprietary name "Ruxoprubart" (pronounced Ruk” soe proo’ bart) for NM8074, designating it as a first-in-class Alternative Pathway selective investigational monoclonal antibody. Administered through the USAN Program, a renowned organization for assigning distinct names to identify pharmaceutically active substances, the name Ruxoprubart reflects a novel nomenclature system for monoclonal antibodies, rooted in antibody type and mechanism of action.

Dr. Rekha Bansal, Chief Executive Officer of NovelMed, expressed, "The assignment of the nonproprietary name to NM8074 represents a significant milestone as we advance this potential PNH treatment towards study completion and regulatory filings. This allows us to establish a well-recognized name for future publications, labeling, and marketing materials." Committed to scientific exploration, NovelMed continues to explore how its leading drug could address unmet needs in the field of PNH. Ruxoprubart, a potent and highly selective investigational drug candidate, targets the complement protein Bb, playing a crucial role in benefiting several complement-mediated diseases.

ABOUT RUXOPRUBART −−−

The USAN Council has officially designated Ruxoprubart as the generic name for NM8074. Distinguishing itself by exhibiting no affinity for Factor B, Ruxoprubart selectively binds to protein Bb. This humanized anti-Bb monoclonal antibody serves as a potent inhibitor of the Alternative Pathway.

Phase I Clinical Trial findings in healthy subjects have affirmed the safety and well-tolerance of NM8074. In all cohorts, complete inhibition of the Alternative Pathway (AP) was attained, with

the duration of AP inhibition exhibiting a dose-dependent pattern. With the successful completion of the phase I trial in healthy volunteers, Ruxoprubart has advanced to phase II trials, concentrating on treatment-naïve PNH patients through a multi-dose regimen. The ongoing Phase II Clinical Trial demonstrates a biweekly multidose regimen in PNH patients that is safe and well-tolerated. To date, six treatment-naïve PNH patients have been administered doses with promising results. Initial findings from the ongoing Phase II Trial suggest that Ruxoprubart shows potential in enlarging PNH clone size and diminishing the necessity for pRBC transfusions by hindering the Alternative Pathway. Both the classical pathway and lipid profiles in the ongoing clinical trial appear to be within normal ranges. The trial aims to enroll a total of 12 treatment-naïve PNH patients, further advancing our comprehension of Ruxoprubart's potential in complement-mediated diseases.

Notably, the Anti-Bb molecule marks a pioneering biologic undergoing testing in treatment-naïve PNH patients. FDA has also approved the initiation of Phase II trials for multiple indications, including C3 Glomerulopathy (C3G) and Atypical Hemolytic Uremic Syndrome (aHUS), with trials scheduled in the United States. Overseas approvals cover trials for PNH within the adult population and aHUS, extending to a pediatric population.

ABOUT PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH) −−−

The dysregulation of the Alternative Pathway (AP) is widely recognized as a pivotal factor influencing the course of PNH. Classified as an orphan disease, PNH presents limited and imperfect treatment options. Current sanctioned treatments either hinder infection clearance or induce hyperlipidemia. PNH is characterized by low PNH-RBC clone size, hemolysis, hemoglobinuria, low hemoglobin levels, elevated LDH, and numerous other symptoms that can lead to premature death if left untreated. Chronic symptoms and multiple organ damage are also prevalent in PNH patients.

While FDA-approved anti-C3, C5, and Factor B drugs exist for PNH treatment with potential symptom management, they are not without significant side effects. The imperative for additional treatment options for PNH, both effective and well-tolerated, remains recognized, with the potential to improve the disease outcome.

ABOUT NOVELMED −−−

NovelMed is dedicated to pioneering novel biologics for diverse complement-mediated diseases. As the first to conceptualize and validate an anti-Bb antibody for chronic complement-mediated and complement-associated disorders, NovelMed advances its leading product candidate through clinical trials, primarily focusing on hemolytic and renal disorders.

“Rooted in a commitment to creativity and compassion, NovelMed aims to deliver transformative therapies reshaping the treatment landscape for patients,” says Mr. Robert Bard, VP of Regulatory Affairs. Positioned as a leader in developing Alternative Pathway (AP)-targeted

therapies, NovelMed is dedicated to tackling debilitating diseases in hematology, ophthalmology, nephrology, dermatology, and neurology.

SEEKING PARTNERSHIP TO ADVANCE THE DEVELOPMENT OF RUXOPRUBART FOR RARE DISEASES
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PNH, a hemolytic disorder resulting in a low PNH-RBC clone size, increased RBC transfusions, elevated LDH values, and decreased hemoglobin values, remains an orphan disease with limited treatment options. NovelMed is actively seeking licensing, investment, partnership, and acquisition opportunities to propel Ruxoprubart through further development and approval across multiple rare disease indications in various countries. For additional information, please visit www.NovelMed.com.

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