

Merus announces final Ruling in inequitable conduct case against Regeneron

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Court Further Rules That Regeneron Engaged in Affirmative Egregious Misconduct

UTRECHT, The Netherlands, Nov. 3, 2015 (GLOBE NEWSWIRE) — Merus B.V., a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics, today announced that the U.S. District Court for the Southern District of New York has issued its full written opinion in the Company's inequitable conduct case against Regeneron Pharmaceuticals, Inc. On August 6, 2015, Judge Katherine B. Forrest ruled that Regeneron engaged in inequitable conduct in connection with obtaining U.S. Patent No. 8,502,018 (the '018 patent), entitled "Methods of Modifying Eukaryotic Cells." In the full written opinion, issued yesterday, Judge Forrest has concluded that Regeneron engaged in inequitable conduct by withholding material information with an intent to deceive the United States Patent and Trademark Office while prosecuting the '018 patent, stating that "[b]ased upon the Court's assessment of the evidence, it appears that the very birth of this patent was beset by misconduct as well. And so it has come full circle. That which was obtained by misconduct ends as a result of misconduct." Judge Forrest further stated that "the disclosures in the specifications of the '018 [p]atent were... insufficient to practice the invention," and based on certain evidence, concluded that Regeneron made false and misleading statements, which constituted egregious affirmative misconduct.

On March 11, 2014, Regeneron filed a complaint against Merus alleging that it infringed one or more claims in the '018 patent. On July 3, 2014, Merus filed a response to Regeneron's complaint, denying Regeneron's allegations of infringement and raising affirmative defenses. Merus also filed counterclaims seeking, among other things, a declaratory judgement that Merus did not infringe the '018 patent and that the '018 patent was invalid. Merus subsequently filed amended counterclaims seeking a declaratory judgement of unenforceability of the '018 patent due to Regeneron's commission of inequitable conduct. Regeneron's '018 patent had previously been adjudged to be not infringed and that it was invalid. Yesterday's final ruling in Merus' favor renders the '018 patent unenforceable for being procured by inequitable conduct.

About Merus B.V.

Merus is a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics, referred to as Biclonics. Biclonics are based on the full-length IgG format, are manufactured using industry standard processes and have been observed in preclinical studies to have several of the same features of conventional IgG-based antibodies, such as long half-life and low immunogenicity. Merus' lead bispecific antibody candidate, MCLA-128 is being evaluated in a Phase 1/2 clinical trial in Europe as a potential treatment for HER2-expressing solid tumors. Merus' second bispecific antibody candidate, MCLA-117, is being developed as a potential treatment for acute myeloid leukemia, and Merus expects to initiate clinical trials of this candidate in the first quarter of 2016. The company also has a robust pipeline of proprietary bispecific antibody candidates in pre-clinical development, including Biclonics designed to bind to various combinations of immunomodulatory molecules, including PD-1 and PD-L1.

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