DRUG DEVELOPMENT TOOL
LETTER OF INTENT
REVIEWABILITY MEMORANDUM
DDT-BMQ-000165

April 30, 2025

Pulmonary Fibrosis Foundation
Attention: Peter Schafer & Jennifer Mefford
223 W Jackson Blvd, Suite 350
Chicago, IL 60606

Dear Mr. Schafer and Ms. Mefford:

FDA has completed the initial assessment of the Letter of Intent (LOI) for Drug Development Tool (DDT), DDT--BMQ-000165, received on April 3, 2025, by the CDER/CBER Biomarker Qualification Program (BQP), submitted under section 507 of the Federal Food, Drug, and Cosmetic (FD&C) Act.[1]

The LOI is for the PROLIFIC Risk Score (the 4-marker panel of SP-D, CXCL13, TNC, and MMP-7), a prognostic biomarker in patients with Idiopathic Pulmonary Fibrosis (IPF) to be used as a stratification factor or as eligibility criteria in clinical trials to identify patients who are more likely to have clinical events or disease progression (an enrichment tool). As the PROLIFIC Risk Score is a composite risk score with specific cut-offs identifying low- and high-risk IPF populations for disease progression.

FDA has determined that your submission is **reviewable**. The review clock will begin on the date of this memorandum. The DDT qualification program aims to communicate their decision in a Determination Letter within **3** months.

Should you have any questions, please contact the CDER Biomarker Qualification Program at CDER-BiomarkerQualificationProgram@fda.hhs.gov.

Sincerely,

Jennifer Borges-Roman, PMP
Regulatory Project Manager
Office of Drug Evaluation Science
Office of New Drugs
Center for Drug Evaluation and Research

[1] In December 2016, the 21st Century Cures Act added section 507 to the FD&C Act. FDA is now operating its DDT programs under section 507 of the FD&C Act.

U.S. FOOD & DRUG ADMINISTRATION

Jennifer Borges-Roman

Digitally signed by Jennifer Borges-Roman

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