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PRESS RELEASE

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NEW MATERIAL TRANSFER AGREEMENT (MTA) BETWEEN THE FDA AND BIOINFOGATE TO ACCESS THE OFF-X TRANSLATIONAL SAFETY INTELLIGENCE PORTAL

The agreement aims to evaluate new approaches to enhance safety assessments of human pharmaceuticals and their associated molecular targets, supporting the FDA's mission of protecting public health.

Barcelona, April 24, 2018

Under this MTA, the FDA will be provided agency-wide access to Bioinfogate's translational safety intelligence portal, OFF-X™. The primary objective of the agreement is to evaluate the potential use of Bioinfogate OFF-X™ as a research tool to anticipate adverse events associated with molecular targets.

Unexpected safety issues constitute one of the most disruptive events in clinical research, and the rapid identification of the potential targets underlying them is crucial. In this context, it is essential to detect as early as possible in the drug R&D process the potential safety liabilities associated to both the primary targets of drugs (i.e. the therapeutic target) as well as those that may be linked to unintended off-target activities (drug interactions distinct from the intended target, also known as secondary pharmacology). Extensive exploration of an investigational drug's polypharmacology space can provide additional clues for specific safety endpoints to be addressed. There is a need for new approaches to enhance early safety assessments that can reduce patient burden and avoid costly failures.

About FDA CDER

FDA/CDER performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. FDA/CDER's mission is to protect and promote public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.

About Bioinfogate OFF-X™

Bioinfogate, a leading data science organization, is the producer of the OFF-X™ portal (https://www.targetsafety.info/). OFF-X™ is the first translational safety intelligence portal that allows drug R&D scientists to be promptly informed about the target modulating effects of small molecules and biologics leading to preclinical toxicity and clinical adverse events. Updated daily with expertly curated safety alerts, OFF-X™ covers more than 5,500 targets in all stages of drug R&D development from emerging and first-in-class targets to targets for drugs that have reached the marketplace. OFF-X™ aims to promptly identify toxicology & safety signals and de-risk R&D programs.

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