

Press Release**BrightInsight Announces the Launch of a
CE-marked Dosing Calculator for Emicizumab**

SAN JOSE, Calif., May 23, 2019, BrightInsight announced the launch of a web-based CE-marked Dosing Calculator for emicizumab, a drug which is prescribed by physicians to treat patients with Hemophilia A. Hemophilia A is a rare disorder in which blood does not clot normally because it lacks sufficient blood-clotting proteins (clotting factors). The development and distribution of the Dosing Calculator for emicizumab is sponsored by F. Hoffmann-La Roche.

To support the usage of emicizumab, BrightInsight has launched a CE-marked Dosing Calculator that will enable Health Care Professionals to input data to determine the correct dosage and number of vials for patients based on the approved recommended dosage. "This is a great initiative for regulated digital health that provides a simple and convenient solution for physicians," said Kal Patel, MD, president & chief executive officer, BrightInsight. "Our medical-grade Internet of Things (IoT) platform enables companies to easily build, deploy and globally scale regulated digital health solutions, including regulated medical apps, algorithms and connected drugs/devices. BrightInsight's Dosing Calculator helps to enable Health Care Practitioners prescribe the correct dosage of emicizumab for people with Hemophilia A and contributes to sustainable product use."

The calculator aids physicians in determining the correct loading and maintenance dose of emicizumab that should be administered based on approved dosing recommendations and inputs of a patients' biometrics. In addition, based on the same inputs, the Hemlibra Dosing Calculator also determines the recommended number of vial(s). BrightInsight built this Dosing Calculator under its ISO 13485:2016 Certified QMS, which can support any classification of medical device (I – III), combination product or Software as a Medical Device (SaMD) in the US and Europe. The Hemlibra Dosing Calculator is a CE-marked SaMD intended for use by Health Care Professionals in Europe.

ABOUT BRIGHTINSIGHT, A FLEX COMPANY

BrightInsight, a Flex Company, provides the leading global regulated digital health platform for biopharma and medtech. Our medical-grade Internet of Things (IoT) platform is built under a robust QMS ISO 13485:2016 to enable regulated drugs, devices and SaMDs to ingest and analyze data and deploy regulated recommendations and insights back to patients and providers. Additionally, the BrightInsight™ Platform captures, transmits and analyzes data from CE-marked and FDA-regulated medical devices,

combination products, apps and Software as a Medical Device, conforming with security, privacy and regulatory requirements such as HITRUST and GDPR.

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