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North America Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

Health Canada

Notice: Availability of Summary Basis of Decision Documents and Regulatory Decision Summaries on the Drug and Health Product Register

The Therapeutic Products Directorate and Biologics and Genetic Therapies Directorate of the Health Products and Food Branch have changed the web-locations of two key pre-market transparency initiatives. Summary Basis of Decision documents (SBDs) and Regulatory Decision Summaries (RDSs) for pharmaceuticals, biologics, and medical devices are now available exclusively on the Canada.ca website through the Drug and Health Product Register (DHPR).

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/announce-annonce/sbd-rds-dhpr-notice-avis-smd-sdr-mrps-eng.php

FDA

Warning Letter related to Clinical Trial in Cellular Therapy

The FDA issued a lengthy warning letter to Northwestern University over the clinical trial practices of its Dr. Richard Burt - for violating regulations governing the proper conduct of clinical studies involving investigational new drugs during his recent stem cell trial. These include failure to ensure that proper toxicity assessments were performed, lack of proper oversight, and failure to promptly report patient deaths to the FDA.

https://ipscell.com/2017/03/fda-warns-northwesterns-richard-burt-on-reporting-patient-deaths-other-issues-in-stem-cell-trials/

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FDA assay predicts ability of mesenchymal stromal cells to suppress immune system activity

Scientists at the U.S. Food and Drug Administration (FDA) Office of Tissues and Advanced Therapies (OTAT) developed an assay that can predict the ability of human mesenchymal stromal cells to suppress immune system activity.

The study used a signature of over 90 morphological features of cells and 16 different measures of certain cell surface proteins and T cell growth factors to rapidly predict future cell behavior.

https://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm548731.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

OTAT seeks Medical Officer for Hematology Clinical Trial review

The FDA's Center for Biologics Evaluation and Research (CBER) is seeking a Medical Officer with clinical specialty in Hematology. The incumbent will be responsible for the evaluation of trials and clinical development programs for investigational biologic products for safety, biological activity, and efficacy.

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm548725.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

User Fee Billable Biologic Products and Potencies Approved Under Section 351 of the PHS Act

This list is intended to include all CBER user fee billable biologic products and potencies approved under Section 351 of the Public Health Service Act and subject to the Prescription Drug User Fee Act (PDUFA).

New, updated list available here:

https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm122936.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Important Information Regarding Zika Virus

The CDC website now includes information about areas with potential increased risk to blood and tissue safety that were identified upon retrospective analysis (in addition to

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listing areas with active transmission). The potential increased risk currently affects those in Florida's Miami-Dade, Broward, and Palm Beach counties from June 15, 2016, forward due to local movement of the population within the contiguous tri-county area.

HCT/P Establishments

https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm546323.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

And

Blood Establishments

https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm546326.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Public Announcements of Industry Filings

Kite Pharma (KITE) completed the rolling submission of its Biologics License Application (BLA) seeking approval of lead CAR-T candidate axicabtagene ciloleucel (KTE-C19) for the treatment of relapsed/refractory aggressive non-Hodgkin lymphoma (NHL). If approved, market launch will commence this year. The filing is the second for a CAR-T in the U.S.

https://seekingalpha.com/news/3254866-kite-completes-filing-u-s-marketing-application-car-t-treat-nhl?app=1&uprof=14

First in the US, Novartis announced that the US FDA has accepted its BLA filing and granted priority review for CTL019 (tisagenlecleucel-T), an investigational CAR-T therapy, in relapsed and refractory (r/r) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (ALL). This is the first BLA submission by Novartis for a CAR-T therapy. The priority review designation is expected to shorten anticipated review time by the FDA.

https://globenewswire.com/news-release/2017/03/29/946535/0/en/Novartis-announces-first-CAR-T-cell-therapy-BLA-for-pediatric-and-young-adult-patients-with-r-r-B-cell-ALL-granted-FDA-Priority-Review.html