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China drug regulator calling on international pharmaceutical companies to bring "urgently-needed" new drugs to China

9 August 2018

On 8 August 2018, in an unprecedented regulatory action, China National Drug Administration (CNDA) (formerly known as CFDA) called on international pharmaceutical companies to bring 48 new drugs to China. These new drugs are viewed to be urgently needed in China and have already been approved and marketed in the U.S., EU and Japan for rare diseases or other life-threatening diseases and conditions. CNDA stated that to the extent the drug sponsors can submit data demonstrating there are no racial or ethnic differences that would affect the efficacy, they are encouraged to submit their new drug applications now without conducting clinical trials in China. Once the drug applications are submitted, the CNDA will prioritize their review. The drug sponsors are also encouraged to schedule meetings with the Center for Drug Evaluation of CNDA if they have any application-related questions.

CNDA's data requirements for the new drug applications can be summarized as follows:

- Proof of approval in U.S., EU, or Japan by corresponding drug regulators; proof of marketing in Japan, Hong Kong, Macau, or Taiwan and export records to these areas for the past five years.
- Application data package meeting the CTD requirements. Certain key documents should be in Chinese.
- Racial sensitivity analysis report based on relevant guidance documents from ICH.
- Post-market research and risk control plan.
- Statement of consistency.

Public comments for the list and new drug application data requirements are due on 18 August 2018. It is unclear at this point whether CNDA will consider additional new drugs to be added to the list. It is also unclear what data CNDA requires to demonstrate no racial or ethnic differences that would affect the efficacy. Regardless, this is yet another encouraging development in China for international pharmaceutical companies.

We will continue to monitor the status of any regulatory changes and reforms by CNDA. With offices in Washington DC and Beijing, and a team of life science attorneys well versed in both FDA and CNDA regulations, Hogan Lovells is well-positioned to assist international pharmaceutical companies in launching their innovative drug products in China. Please contact one of the authors of this alert if you have any questions or if we can be of further assistance.

Appendix:

List of Drugs Urgently Needed in China (unofficial translation by Hogan Lovells US LLP) (Source: http://www.cde.org.cn/news.do?method=viewInfoCommon&id=314651.)			
Serial #	**Drug name**	**Sponsor/license holder**	**First approval date outside of China (jurisdiction)**
1	Alectinib Hydrochloride	Chugai Pharmaceutical Co., Ltd.	2014/7/4 (Japan)
2	Pembrolizumab	Merck Sharp & Dohme Corp.	2014/9/4 (U.S.)
3	Olaparib	AstraZeneca AB	2014/12/16 (EU)
4	Evolocumab	Amgen Europe B.V.	2015/7/15 (EU)
5	Siltuximab	Janssen Biotech, Inc.	2014/4/23 (U.S.)
6	Elosulfase Alfa	Biomarin Pharmaceutical Inc.	2014/2/14 (U.S.)
7	Selexipag	ActelionPharmaceuticalsLtd	2015/12/21 (U.S.)
8	Brodalumab	Kyowa Hakko Kirin Co., Ltd.	2016/7/4 (Japan)
9	Eculizumab	Alexion	2007/6/20 (EU, U.S.)
10	Canakinumab	Novartis Pharmaceuticals Corporation	2009/6/17 (U.S.)
11	Denosumab	Amgen Europe B.V.	2010/5/26 (EU)
12	Fingolimod Hcl Ora Lcapsules	Novartis Pharmaceuticals Corp	2010/9/21 (U.S.)
13	Teriflunomide		2012/9/12 (U.S.)
14	Ponatinib	Ariad Pharmaceuticals Inc	2012/12/14 (U.S.)
15	Vedolizumab	Takeda Pharmaceuticals U.S.A., Inc.	2014/5/20 (U.S.)
16	Eliglustat	Genzyme Corp	2014/8/19 (U.S.)
17	Secukinumab	Novartis Pharma K.K.	2014/12/26 (Japan)
18	Palbociclib	Pfizer,Inc	2015/2/3 (U.S.)
19	Ixekizumab	ELILILLYANDCOMPANY	2016/3/22 (U.S.)
20	Enasidenib mesylate	CELGENECORP	2017/8/1 (U.S.)
21	Icatibant	Shire Orphan Therapies GmbH	2008/7/11 (EU)
22	Dalfampridine	Acorda Therapeutics Inc	2010/1/22 (U.S.)
23	Vismodegib	Genentech Inc	2012/1/30 (U.S.)
24	Apremilast	Celgene Corp	2014/3/21 (U.S.)
25	Rilonacept	Regeneron	2008/2/27 (U.S.)
26	Tetrabenazine	Prestwick	2008/8/15 (U.S.)
27	Ecallantide	Dyax Corp.	2009/12/1 (U.S.)
28	Velaglucerase Alfa	Shire Human Genetic Therapies Inc	2010/2/26 (U.S.)
29	Tafamidis	Pfizer Ltd	2011/11/16 (EU)
30	Taliglucerase Alfa	Pfizer Inc	2012/5/10 (U.S.)
31	Lomitapide	Aegerion Pharmaceuticals Inc	2012/12/21 (U.S.)
32	Mipomersen Sodium	Genzyme Corp	2013/1/29 (U.S.)
33	Dinutuximab	UnitedTherapeuticsCorporation	2015/3/10 (U.S.)
34	Sonidegib	NovartisPharmaceuticalsCorp	2015/7/24 (U.S.)
35	Olaratumab	ELILILLYANDCOMPANY	2016/10/19 (U.S.)
36	Nusinersen	BIOGENIDECINC	2016/12/23 (U.S.)

Serial #	Drug name	Sponsor/license holder	First approval date outside of China (jurisdiction)
37	Deutetrabenazine	TEVABRANDEDPHARM	2017/4/3 (U.S.)
38	Dinutuximab Beta	EUSA Pharma (UK) Limited	2017/5/8 (EU)
39	Recombinant Human Nerve Growth Factor (Rhngf)	Dompe farmaceutici s.p.a.	2017/7/6 (EU)
40	Guselkumab	JANSSENBIOTECH	2017/7/13 (U.S.)
41	Vestronidase Alfa-Vjbk	ULTRAGENYXPHARMINC	2017/11/15 (U.S.)
42	Shingrix Zoster Vaccine Recombinant, Adjuvanted	GlaxoSmithKline Biologicals Rue de l"Institut 89, B1330 Rixensart, Belgium Lic # 1617	2017/10/20 (U.S.)
43	Luxturna Voretigene Neparvovec	Spark Therapeutics, Inc. 3737 Market Street, Suite 1300, Philadelphia, PA, 19104 Lic# 2056	2017/12/19 (U.S.)
44	Vernakalant Hydrochloride	Cardiome UK Limited	2010/9/1 (EU)
45	Vorapaxar	Merck Sharp And Dohme Corp	2014/5/8 (U.S.)
46	Ledipasvir And Sofosbuvir	Gilead Sciences Inc	2014/10/10 (U.S.)
47	Sofosbuvir; Velpatasvir; Voxilaprevir	GILEADSCIENCESINC	2017/7/18 (U.S.)
48	Elvitegravir, Cobicistat, Emtricitabine, And Tenofovir Alafenamide	GileadSciencesInc	2015/11/5 (U.S.)

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