Health Canada / Santé Canada

Health Products and Food Branch / Direction générale des produits de santé et des aliments

INTERIM ORDER– TERMS AND CONDITIONS
Company: GlaxoSmithKline Inc.
Product: sotrovimab
Dossier ID: HC6-024-E246705

Background:

The Interim Order allows the Minister to impose or amend terms and conditions, and request additional information, in relation to a COVID-19 drug submission, authorization, or establishment licence, at any time while it is in effect. In light of the severity of the COVID-19 pandemic, this allows the Minister to act quickly to gather important safety information or mitigate risk in a timely manner.

Depending on the requirement, terms and conditions can be ongoing (e.g., require a monthly report), have a defined time (e.g., a report is due to Health Canada on a specific day) or are to be completed once the data is available (e.g., a clinical trial is completed).

The status of the Terms and Conditions will be updated on a regular basis.

Status as of July 30, 2021:

Total Number: 15

Ongoing/pending: 15

Closed: 0

Table: Terms and Conditions

	Terms and Conditions	Issued	Status
1	Provide a complete reporting of the COMET-ICE clinical study with study number VIR-7831-5001 (GSK Study 214367), titled: A Phase II/III randomized, multi-center, double-blind, placebo-controlled study to assess the safety and efficacy of monoclonal antibody VIR-7831 for the early treatment of coronavirus disease 2019 (COVID-19) in non-hospitalized patients. The complete report(s) should provide the final analyses of efficacy and safety from all phases and cohorts. The information should include complete clinical study reports and associated documentation in accordance with the relevant International Council for Harmonisation (ICH) guidelines (e.g., ICH E3, ICH M4).	July 30, 2021	Pending availability of data

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2	Provide, when available, clinical study reports for the following clinical trials. The information should include complete clinical study reports and associated documentation in accordance with the relevant International Council for Harmonisation (ICH) guidelines (e.g., ICH E3, ICH M4). The sponsor should provide the estimated date of study completion and the estimated date of submission. a. COMET-TAIL (study number VIR-7831-5008), titled: A Phase 3 randomized, multi-center, open label study to assess the efficacy, safety, and tolerability of monoclonal antibody VIR-7831 (sotrovimab) given intramuscularly versus intravenously for the treatment of mild/moderate coronavirus disease 2019 (COVID-19) in high-risk non-hospitalized patients. b. COMET-PACE: Currently planned to assess the pharmacokinetics and safety of sotrovimab in children from birth to < 18 years of age with mild to moderate COVID-19 at high risk of disease progression.	July 30, 2021	Pending availability of data
3	Provide regular updates to Health Canada regarding the activity and/or clinical efficacy/effectiveness of sotrovimab against the current and future variants of concern and variants of interest identified by the World Health Organization (WHO). Data will be submitted upon availability when additional variants of interest/variants of concern are identified by WHO. The WHO lists variants of concern and variants of interest in its weekly epidemiological update on COVID-19, which can be accessed on its website: *https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports*	July 30, 2021	Pending availability of data
4	Provide updates on US and European regulatory strategies, including anticipated timelines, for conditional and full marketing authorization applications at least twice per year.	July 30, 2021	Ongoing
5	Provide information as it becomes available regarding any failed, or aborted Drug Substance or Drug Product lots. The information should include a detailed description of the issue(s) associated with the lot and a discussion on any potential impact on quality, safety and efficacy of lots that have already been manufactured at the facility and sites.	July 30, 2021	Ongoing
6	Within 2 weeks of receiving the Interim Order (IO) authorization, provide an estimated date by which the amendment to transfer the Drug Substance manufacture to the site will be filed with Health Canada.	July 30, 2021	Expected by August 13, 2021
7	Within 2 weeks of receiving the IO authorization, provide the Continued Process Verification (CPV) plan to the Biologic and Radiopharmaceutical Drugs Directorate (BRDD). Any updates to the CPV plan should also be provided within 2 weeks of the revision update.	July 30, 2021	Ongoing
8	Within 2 weeks of its finalization, provide the Drug Substance process performance qualification (PPQ) reports for Drug Substance manufactured at the facility, any overarching validation summary reports, and any ancillary validation reports (e.g. hold time validation, extractables and leachables).	July 30, 2021	Pending availability of data

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9	Within 2 weeks of their finalization, provide an English-language summary of the Italian-language Drug Product Process validation reports and any overarching validation summary reports for Drug Product manufactured at the site. The English—language summary should include all the data from the PPQ campaign, including release data for the PPQ lots, to enable a comprehensive analysis of process consistency.	July 30, 2021	Pending availability of data
10	Within 2 weeks of finalization, provide the analytical method validation reports and any necessary method transfer reports for the non-compendial release and stability methods.	July 30, 2021	Pending availability of data
11	Within 2 weeks of finalization of each stability report update, provide the updated stability report and a critical assessment of the data, along with a request for extension of Drug Substance and/or Drug Product expiry dates, if warranted by the data.	July 30, 2021	Pending availability of data
12	After authorization under the Interim Order (IO) and commencing August 1, 2021, submit monthly safety reports for the period of the interim authorization, unless otherwise determined by Health Canada.	July 30, 2021	Ongoing
13	GlaxoSmithKline Inc. to submit final snapshots of all components of the electronic platform (linked to on the foreign and Canadian specific labels) relevant to Canadian users of sotrovimab. This content includes Canadian-specific labelling information for sotrovimab in French and English for Health Canada's review and records, prior to launch of the electronic platform and for each subsequent update.	July 30, 2021	Pending
14	GlaxoSmithKline Inc. to develop and distribute a Health Product Risk Communication (HPRC), in French and English, with Health Canada approval and endorsement, to inform healthcare professionals about the authorization of the sotrovimab under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* with foreign labels for the initial supply, to expedite global access of the drug in the context of the pandemic. a. The letter should direct healthcare professionals to the electronic platform where they can find information about Canadian-specific labelling in both official languages and should be issued prior to, and in bulk alongside shipment of sotrovimab from the GlaxoSmithKline Inc. (GSK) warehouse, until such a time that Canadian specific labelling is implemented. b. The letter should include an alternative method for the health care professionals to obtain a paper copy of the Product Monograph by mail or fax from GlaxoSmithKline Inc., if they cannot access the internet.	July 30, 2021	Pending
15	GlaxoSmithKline Inc. to implement Canadian-specific bilingual labelling for sotrovimab once supplies are transitioned to Canadian dedicated supplies. Health Canada should be kept informed of estimated timelines and proposed strategies concerning the implementation of Canadian-specific bilingual labels.	July 30, 2021	Pending

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	a. During the period prior to implementation of the Canadian-specific bilingual labeling, approved mock-ups of the proposed Canadian labels should be made available to healthcare professionals as reference.		