Requests for Expanded Access to Unapproved Drugs in the U.S.

Constellation Pharmaceuticals' Policy for Requests for Expanded Access to Unapproved Drugs describes the principles and procedures that the company will follow when considering requests by physicians for use of unapproved Constellation Pharmaceuticals drugs outside of clinical trials. Please see below for further details.

I. Constellation Pharmaceuticals Policy for Evaluating Expanded Access to Unapproved Drugs Outside of Constellation Pharmaceuticals Clinical Trials

Constellation Pharmaceuticals is currently testing in clinical trials investigational compounds (aka drugs) that have not yet been approved by the United States (U.S.) Food and Drug Administration (FDA) or any other Health Authority (HA) for commercial sale.

We conduct research on our investigational drugs so that we can better understand how they work, obtain proof that they are safe and effective, with the ultimate aim to achieve approval from FDA and other HAs to make these drugs available commercially to patients. Our scientific and ethical obligations to our patients, healthcare professionals and stakeholders are to conduct this clinical research as efficiently and effectively as possible.

On rare occasions, physicians may identify patients with serious diseases or conditions who cannot participate in our clinical trials but who may benefit from one of our unapproved compounds. In such situations, Constellation Pharmaceuticals will on a case by case basis consider requests from physicians to supply an unapproved drug to a specifically identified patient.

Constellation Pharmaceuticals will evaluate such requests in a scientifically and ethically responsible way according to the principles and procedures set forth below and applicable government regulations.

1. The unapproved drug must be in active clinical development. Constellation Pharmaceuticals must be actively studying the investigational therapy in Phase 2 or later in the U.S. conducted under a U.S. IND or under international regulations in other countries if requests come from outside of the US.

2. The patient must have a serious disease or condition. A serious disease or condition is defined in FDA's expanded access regulations as follows:

> . . . a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible if it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. (ref 21 CFR 312.300(b))

3. The request for use of the investigational drug must be within the use being studied in the clinical trials. The request for use of the investigational drug must not interfere with the initiation, conduct, or completion of the clinical development program being run by Constellation Pharmaceuticals.

4. Patients must have tried to join our clinical trials of the unapproved drug. Clinical trials are the customary way in which patients access unapproved compounds. Constellation Pharmaceuticals has a scientific and ethical obligation to complete clinical trials, and, when appropriate based on risk and clinical benefit considerations for a specific population, apply to Health Authorities for regulatory approval, in order to offer compounds to a wider population of patients commercially if approved.

Clinical trials are conducted by Physicians trained on the use of, and potential risks associated with, our unapproved drugs. Therefore, as a precondition for any request for access to our investigational drug outside of clinical trials, a patient must have been considered for enrollment into a clinical trial of the unapproved drug. If, however, a patient does not meet the criteria for participation in clinical trials or recruitment of the clinical trials has been completed, a patient might or might not receive the unapproved drug through expanded access.

5. The potential clinical benefit must justify the potential risks of drug use and those potential risks must not be unreasonable in the context of the disease or condition to be treated.

6. The physician requesting access must be licensed and qualified to prescribe, and if applicable administer the investigational drug, agree to directly supervise treatment, be willing to obtain an IND from FDA (with cross-referencing to the Constellation IND), otherwise comply with relevant US federal and state regulations, and agree to follow Constellation Pharmaceuticals policies applicable to expanded use in general and any conditions or restrictions set by Constellation Pharmaceuticals for the particular drug and patient.

7. The physician requesting access must provide:

- A persuasive scientific rationale for the theoretical benefit that the unapproved drug could provide
- A statement that all approved therapies typically used to treat the disease have been exhausted and that the patient is no longer responsive to, or able to tolerate, these therapies
- A statement that there are no other viable therapy options, including participation in other ongoing relevant clinical trials

8. There must be enough clinical data to identify an appropriate dose (amount and frequency of the unapproved drug given) and appropriate formulation.

9. After meeting the needs of clinical trials, Constellation Pharmaceuticals must have a sufficient supply of the unapproved compound to reasonably accommodate the likely duration of treatment.

10. The physician and patient must agree to waive claims for damages against Constellation Pharmaceuticals, Inc.

II. Procedure for Requesting Expanded Access and Response Times

1. Treating physicians interested in treating a patient with a Constellation Pharmaceuticals unapproved drug that is in active clinical development must accept the acknowledgement described in Section IV below.

2. When the necessary information has been satisfactorily completed and submitted to Constellation Pharmaceuticals through the email address shown below and the company will usually acknowledge receipt via email within four weeks of receiving the request.

3. Making a request does not guarantee the granting of access to an unapproved drug.

Constellation Pharmaceuticals will review each request on a case-by-case basis. The decision to grant

access is solely Constellation Pharmaceuticals' decision. Constellation Pharmaceuticals also reserves the right to terminate the supply of drug at any time.

III. Contact for Further Information and Link to ClinicalTrials.Gov

For patients that meet Constellation's criteria for expanded access, treating physicians can make a request to Constellation at expandedaccess@constellationpharma.com .

Information regarding Constellation's pipeline of investigational drugs can be found at www.constellationpharma.com/our-programs/#pipeline. Information regarding specific Constellation clinical studies can be found at https://clinicaltrials.gov.

IV. Acknowledgements of Applicants for Expanded Access to Constellation Pharmaceuticals' Investigational Drugs

The following must be read, understood and accepted in writing by the referring physician applicant.

1. I am a physician duly licensed and authorized to practice medicine in the jurisdiction in which I intend to administer an investigational drug.

2. I will use the investigational drug only for the named patient for whom the supply of investigational drug is being requested.

3. I acknowledge that this investigational drug will be provided to the named patient under my direct personal responsibility and I am responsible for all communications with the patient.

4. I will obtain any required approvals of governmental authorities applicable to use of investigational drugs.

5. I will obtain the informed consent of the patient or patient's legally acceptable representative in accordance with applicable laws and regulations before giving the first dose of the investigational drug to the patient.

6. I will ensure that the informed consent authorizes the transfer of study data to Constellation Pharmaceuticals or its representatives for research or regulatory purposes

7. I will inform my patient of the risks associated with the investigational drug, including that it has not been approved in this country, prior to the first administration of the investigational drug.

8. I will notify and/or obtain approval from the institutional review board/independent ethics committee regarding the use of the investigational drug for the patient specified in the request, if required by applicable laws and regulations or institutional requirements.

9. I confirm that I have asked and obtained consent from the patient to the collection and use of any personal data and communication of such data to regulatory authorities to the extent necessary to comply with local laws.

10. I acknowledge that I am responsible for reporting all adverse events associated with use of the investigational drug, regardless of my causality assessment, to Constellation Pharmaceuticals. I will notify Constellation Pharmaceuticals within 24 hours of my becoming aware of any Serious Adverse Event as defined by the FDA, fatal event, or immediately life-threatening adverse event and within 10 days of my becoming aware of all other adverse events including hospitalization of the patient.

11. I will maintain the confidentiality of information provided about the investigational drug and disclose or disseminate such information only as required by law or regulation or as authorized by Constellation Pharmaceuticals.

12. I agree that Constellation Pharmaceuticals may use data and results generated as a result of the administration of the investigational drug to patients for any purpose in accordance with applicable laws, and that Constellation Pharmaceuticals will own all resulting patent or other intellectual property rights.

13. I will adhere to all applicable local laws and regulations.

14. I will inform Constellation Pharmaceuticals when the patient specified in the request is no longer receiving treatment with the requested investigational drug.

15. I will provide Constellation Pharmaceuticals any written summaries that are provided to local regulatory authorities at the conclusion of treatment with the investigational drug, including adverse events.

16. I will submit any publication material to Constellation Pharmaceuticals prior to submission, for review and approval.

17. I release from liability and waive my right to sue Constellation Pharmaceuticals for all claims that may result from my use of the investigational drugs and any events incidental to this use.

Please submit a certification I certify that you have read, understood and accept the above acknowledgments ((“I certify that I have read, understood and accept the above acknowledgements”) by email to expandedaccess@constellationpharma.com .