Effective Health Care
Scientific Resource Center
AHRQ Funded by the Agency for Healthcare Research and Quality

Portland VA Research Foundation
Scientific Resource Center
PO Box 69539
Portland, OR 97239
www.effectivehealthcare.ahrq.gov

January 24, 2021

Re: Request for Scientific Information on «OfficialTitle»

«FirstName» «LastName»

The Agency for Healthcare Research and Quality (AHRQ) is seeking to verify the completeness of our information and obtain any missing data on: «Drugs». Evidence and data are being solicited to supplement our dataset and inform our review of «OfficialTitle», which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program.

This letter requests from «Company» evidence and data from *ALL studies intended to determine efficacy including premarketing studies (phase II and above clinical trials), post-marketing studies, observational studies, and comprehensive reports* related to «Drugs»:

- A list of all completed studies your organization has sponsored for this indication. In the list, *indicate whether the study is registered on ClinicalTrials.gov by providing the NCT number (or "N/A" if not registered), and please indicate whether results are posted on ClinicalTrials.gov*.
  - *For completed studies that are registered on ClinicalTrials.gov, but do not have results, please provide a summary*. This summary should include: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number if available. If the trial is not registered, please provide the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- A statement as to whether the above studies constitute *ALL studies intended to determine efficacy including premarketing studies (phase II and above clinical trials), post-marketing studies, observational studies, and comprehensive reports* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Please submit material on or before [4 weeks from mail date] 11:59pm EST for consideration in this report. Material submitted after this date will be considered in any subsequent report updates.

Please submit materials via our online submission form: [online submission form URL]. Select the study for which you are submitting information from the list to complete the form and upload documents. You can also e-mail them to Ryan McKenna at sips@epc-src.org.

If you wish to submit hardcopy materials, please mail them to:

Mailing Address
Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
PO Box 69539
Portland, OR 97239

Shipping Address (FedEx, UPS, etc.)
Portland VA Research Foundation

Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
3710 SW U.S. Veterans Hospital Road

Mail Code: R&D 71
Portland, OR 97239

If you are not the appropriate contact for this request, please forward this letter to the proper individual. Please don't hesitate to contact Ryan McKenna at sips@epc-src.org or call 503-220-8262 ext. 58653 if you have a question or comment.

Additional background information is available in the attached Key Questions and the study's research protocol: [**INSERT RESEARCH PROTOCOL URL HERE**].

Access to published and unpublished pertinent scientific information on your product(s) will improve the quality of this review. AHRQ is conducting this research pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law108-173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

Your contribution is very beneficial to the Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; pharmacoeconomic, pharmacokinetic or pharmacodynamic studies; study types not included in the review; or information on indications not included in the review cannot be used by the Effective Health Care Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The program is dedicated to identifying as many studies as possible that are relevant to the key questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information (e.g., details of studies conducted) from relevant pharmaceutical industry stakeholders.

The draft of this review will be available for public comment as part of the peer review process via the Effective Health Care website. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: http://effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/.

Thank you for your willingness to participate in the AHRQ Effective Health Care program.

Sincerely,

Mark Helfand, MD, MPH
Scientific Resource Center for the
AHRQ Effective Health Care Program

Attached:«OfficialTitle» Key Questions