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AMENDMENT #1 TO THE
COLLABORATIVE STUDY AGREEMENT

First Amendment (the "Amendment") to that certain Collaborative Study Agreement (this "Agreement") and incorporated herein by reference) effective December 28, 2015 between American Research Corporation at The Texas Liver Institute (the "Institution") and AbbVie Inc. ("ABBVIE").

Subject to the full execution of this Amendment, ABBVIE and Institution hereby agree to the following amendment:

DocuSign Envelope ID: 5AF431D3-75AE-4EB8-A199-FEA76F7ED99C

American Research Corporation
at The Texas Liver Institute
Fred Poordad, M.D.

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IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

ABBVIE INC.


DocuSigned by:
By: Susan M. Buttler
Name: Signer Name: Susan M Buttler
Signing Reason: I approve this document
Signing Time: 1/7/2019 2:01:37 PM CST
Title: Director, Outsourcing
A79DE727651A4E1A63C40D85A6FC17B
Date:

DocuSigned by:
CRS
Signer Name: CRS Group
Signing Reason: I approve this document
Signing Time: 1/7/2019 1:53:19 PM CST
D9E8D77E3DB04784834E6136697CA68B

AMERICAN RESEARCH CORPORATION AT THE
TEXAS LIVER INSTITUTE

By: 
Name: Eric Lawitz
Title: Medical Director
Date: 12/21/2018

I have read this Agreement and acknowledge the obligations under the provisions of the Agreement.

By: 
Name: Fred Poordad, M.D.
Title: Institution Investigator
Date: 12/20/2018

American Research Corporation
at The Texas Liver Institute
Fred Poordad, M.D.

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EXHIBIT A

SCOPE OF WORK

Institution will be responsible or share responsibility with AbbVie as agreed upon by both parties for the following activities in relation to the Study:

- Study Design / Protocol Development
- Regulatory Responsibilities
- Study Conduct
- Data Collection and Management
- Analysis and Interpretation of Results
- Publication and Presentation of Results
- Viekira Pak Study Drug (AbbVie only)

Estimated Study Timelines:

- First Patient In – January 2016
- Last Patient In – March 2016
- Interim data Viral Hepatitis Congress (Frankfurt, Germany – September 2016)
- Final Study report December 2016
- Final Data presented CROI Feb 2017
- Manuscript submitted Q1 2017

Study Synopsis / Description:

Protocol Title	A study to investigate HCV response rates in real world patients traditionally excluded from clinical trials: The HEARTLAND Study
Protocol Number	TLI_IIS_01_2015
Phase of Development	Phase IV
Objectives	<p><u>Primary Objective</u></p> <p>To evaluate the safety and efficacy of OMB/PTV/r + DSV +/- RBV in a real world urban clinical setting in patients who have historically been excluded from clinical trials.</p> <p><u>Secondary Objectives</u></p> <ol style="list-style-type: none"> 1. To evaluate the effect of baseline variants on SVR12 in patients treated with OMB/PTV/r + DSV +/- RBV in a real world urban clinical setting. 2. To evaluate patient reported outcomes in patients receiving OMB/PTV/r + DSV +/- RBV in a real world setting. 3. To evaluate adherence in patients receiving OMB/PTV/r + DSV +/- RBV in a real world setting.
Trial Design	This is a Phase IV, open label, single center study of OMB/PTV/r + DSV +/- RBV for 12 or 24 weeks for the treatment of chronic HCV-1

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