



**Study Number TTP814-102**

A Multi-Centre, Randomized, Double-Blind, Multiple-Ascending-Dose Trial to Evaluate the Safety, Tolerability and Pharmacokinetics of Orally-Administered TTP814 Capsules in Male Volunteers with Type 2 Diabetes.

I \_\_\_\_\_ (Patient's Name) hereby authorize my physician Dr. \_\_\_\_\_ to release the information listed below on my behalf to DecisionLine Clinical Research.

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

**PART A: PRIMARY PHYSICIAN'S CONFIRMATION OF PATIENT'S ELIGIBILITY**

Your patient has expressed interest in participating in a clinical trial sponsored by TransTech Pharma, Inc. Please complete this form to confirm your patient's medical history. The information you provide will only be used to assess your patient's eligibility for the abovementioned study.

This patient has confirmed Type II Diabetes (according to the Canadian Diabetes Association criteria) for at least 6 months prior to the above date

YES  NO

This patient has never been prescribed insulin therapy

YES  NO

This patient has not taken any oral anti-diabetic agents (except metformin, if applicable) in the past 3 months. If your patient is on metformin, please see Part B below.

YES  NO

Please list all of the patient's currently prescribed medications, including oral anti-diabetic agents (if applicable):

- |          |          |
|----------|----------|
| 1. _____ | 5. _____ |
| 2. _____ | 6. _____ |
| 3. _____ | 7. _____ |
| 4. _____ | 8. _____ |

**PART B: ONLY FOR PATIENTS ON METFORMIN**

My patient is on metformin and can safely discontinue therapy for 33 days (for 2 weeks prior to first dosing, until study completion)

YES  NO

I may be contacted by the Principal Investigator or Sub-Investigator to confirm that \_\_\_\_\_

\_\_\_\_\_ (patient's name) can safely discontinue treatment with metformin in order to participate in this study.



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Discontinuation from treatment includes a 14-day washout period prior to study drug treatment and a 14-day study treatment period. During the washout period, the patient will be provided with a Lifescan One Touch Ultra meter to measure and record his fasting blood glucose levels each morning.

The patient will be instructed to contact the study site if his fasting blood glucose levels are

- 1) above 12 mmol/L for more than half of the days in a week ( $\geq 4$  days),
- 2) if a reading is greater than 15 mmol/L and there is no explanation for this elevation, or
- 3) if a reading is less than 3.1 mmol/L at any time.

As an added safety measure, the study site will call the patient undergoing washout from metformin 7 days prior to the study treatment period to review his glucose measurements, to address any concerns with the use of the Ultra meter, and to ask questions about adverse events and concomitant medications.

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Physician's Signature

CPSO#

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Print Name

Telephone #

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Address