Supplementary Material

Pharmacokinetic assessment and treatment effect of lusutrombopag in Child-Pugh Class C patients: review of patient data from two clinical studies and post-marketing surveillance

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| 8KZ  | Wojewódzki Szpital Specjalistyczny im. J. Gromkowskiego, I Oddział Chorób Zakaźnych ul. Koszarowa 5 Wroclaw Poland 51-149 | Instituto Médico de la Fundación Estudios Clínicos Italia 428 Rosario Santa Fe Argentina 2000 | (Formerly Julio Anacleto Gutierrez) American Research Corporation at Texas Liver Institute 607 Camden St. San Antonio Texas United States 78215 |
| 8LA  | Rawi Hazzan HaEmek Medical Center Gastroenterology Department 21 Yitzhak Rabin Ave. Afula Israel 1834111 | Soon-Ho Um Korea University Anam Hospital 73, Inchon-ro Seongbuk-gu Seoul Korea 136-705 | Manuel I. Rodriguez-Davalos Contact Information 333 Cedar St FMB 121 New Haven Connecticut United States 06520 Study site locations Yale University School of Medicine Yale Physician's Building 800 Howard Ave New Haven Connecticut United States 06520 Yale New Haven Hospital 20 York Street New Haven Connecticut United States 06504 |
| 8LC  | Yoav Lurie Shaare Zedek Medical Center Liver Unit, Institute of Gastroenterology 12 Bayit Shmuel St. Jerusalem Israel 9103102 | Mordechai Rabinovitz Contact Information 3471 Fifth Avenue 916 Kaufmann Building Pittsburgh Pennsylvania United States 15213 Study site location Center for Liver Diseases UPMC, MUH, 7 South Frank Sarris Outpatient Clinic 3459 Fifth Avenue Pittsburgh Pennsylvania United States 15213 | Galyna Dubyn'ska Contact Information 22, Prosp.Pershotravnevyi Av. Poltava Poltava Ukraine 36000 Study site locations Poltava Regional Clinical Infectious Hospital, Department of Diagnostics, Higher State Educational Institution of Ukraine 22, Prosp.Pershotravnevyi Av. Poltava Poltava Ukraine 36000 |
| Phase 1-2 | 4AC | 4CB | 4CQ |
|----------|-----|-----|-----|
| Kunihiko Tsuji, MD | Takashi Ueno, MD | Kenji Ikeda, MD |
| Teine Keijinkai Hospital | Isesaki Municipal Hospital | Toranomon Hospital |
| 12-1-40, Maeda 1-jo, Teineku, Sapporo-city, Hokkaido, Japan | 12-1 Tsunatori-honmachi, Isesaki-city, Gunma, Japan | 2-2-2 Toranomon, Minato-ku, Tokyo, Japan |

| 4CK | 4CY | 4CZ |
|-----|-----|-----|
| Masayuki Kurosaki, MD | Kazushi Numata, MD | Hisashi Hidaka, MD |
| Musashino Red Cross Hospital | Yokohama City University Medical Center | Kitasato University Hospital |
| 1-26-1 Kyounan-cho, Musashino-city, Tokyo, Japan | 4-57 Urafune-cho, Minami-ku, Yokohama-city, Kanagawa, Japan | 1-15-1 Kitasato, Minami-ku, Sagamihara-city, Kanagawa, Japan |

| 4EA | 4CW | 4FA |
|-----|-----|-----|
| Tetsuya Mine, MD | Masahiro Kobayashi, MD | Minoru Sakamoto, MD |
| Tokai University, School of Medicine | Toranomon Hospital | University of Yamanashi Hospital |
| 143 Shimokasuya, Isehara-city, Kanagawa, Japan | Kajigaya 1-3-1 Kajigaya, Takatsu-ku, Kawasaki-city, Kanagawa, Japan | 1110 Shimokato, Chuo-city, Yamanashi, Japan |

| 4FF | 4FH | 4FJ |
|-----|-----|-----|
| Hidenori Toyoda, MD | Fumihiro Urano, MD | Yoshiyuki Takei, MD |
| Ogaki Municipal Hospital | Toyohashi Municipal Hospital | Mie University Hospital |
| 4-86 Minaminokawa-cho, Ogaki-city, Gifu, Japan | 50 Aza Hachiken Nishi, Aotate-cho, Toyohashi-city, Aichi, Japan | 2-174 Edobashi, Tsu-city, Mie, Japan |

| 4GB | 4HB | 4GE |
|-----|-----|-----|
| Yoshihide Ueda, MD | Shinji Katsushima, MD | Yukio Osaki, MD |
| Kyoto University Hospital | National Hospital Organization | Osaka Red Cross Hospital |
| 54 Shogoinkawahara-cho, Sakyo-ku, Kyoto-city, Kyoto, Japan | Kyoto Medical Center 1-1 Fukakusamukaihatacho, Fushimi-ku, Kyoto-city, Kyoto, Japan | 5-30 Fudegasaki-cho, Tennojiku, Osaka-city, Osaka, Japan |

| 4GH | 4HC | 4GL |
|-----|-----|-----|
| Takumi Igura, MD | Yukinori Yamada | Atsushi Housui, MD |
| Ikeda City Hospital |
|---------------------|
| 3-1-18, Jonan, Ikeda-city, Osaka, Japan |

| Kaizuka City Hospital |
|-----------------------|
| 3-10-20 Hori, Kaizuka-city, Osaka, Japan |

| Osaka Rosai Hospital |
|----------------------|
| 1179-3 Nagasone-cho, Kitaku, Sakai-city, Osaka, Japan |

| 4GR |
|------|
| Hiroki Nishikawa, MD |
| Hyogo College of Medicine Hospital |
| 1-1 Mukogawa-cho, Nishinomiya-city, Hyogo, Japan |

| 4GT |
|------|
| Tetsuro Inokuma, MD |
| Kobe City Medical Center General Hospital |
| 2-1-1 Minatojimaminamimachi, Chuo-ku, Kobe-city, Hyogo, Japan |

| 4HE |
|------|
| Jun Mimura, MD |
| Nishi-Kobe Medical Centre 5-7-1 Koujidai, Nishi-ku, Kobe-city, Hyogo, Japan |

| 4GZ |
|------|
| Masanori Kawaguchi, MD |
| Saiseikai Wakayama Hospital |
| 45 Junibancho, Wakayamacity, Wakayama, Japan |

| 4JK |
|------|
| Keiko Hosho, MD |
| Tottori University Hospital |
| 36-1 Nishi-cho, Yonago-city, Tottori, Japan |

| 4CN |
|------|
| Kazuya Kariyama, MD |
| Okayama City Hospital 3-20-1 Kitanagase, Omotemachi, Kita-ku, Okayama-city, Okayama, Japan |

| 4JG |
|------|
| Yoshiiku Kawakami, MD |
| Hiroshima University Hospital |
| 1-2-3 Kasumi, Minami-ku, Hiroshima-city, Hiroshima, Japan |

| 4KB |
|------|
| Mitsuyasu Yano, MD |
| Tokushima Prefectural Central Hospital |
| 1-10-3 Kuramoto-cho, Tokushima-city, Tokushima, Japan |

| 4KA |
|------|
| Koichi Takaguchi, MD |
| Kagawa Prefectural Central Hospital |
| 1-2-1 Asahimachi, Takamatsucity, Kagawa, Japan |

| 4KH |
|------|
| Kouji Joko, MD |
| Matsuyama Red Cross Hospital |
| 1 Bunkyo-cho, Matsuyamaicity, Ehime, Japan |

| 4KG |
|------|
| Masashi Hirooka, MD |
| Ehime University Hospital Shitsukawa,Toon-city, Ehime, Japan |

| 4LB |
|------|
| Shusuke Morizono, MD |
| Saiseikai Fukuoka General Hospital |
| 1-3-46 Tenjin, Chuo-ward, Fukuoka-city, Fukuoka, Japan |

| 4LA |
|------|
| Shotaro Sakisaka, MD |
| Fukuoka University Hospital 7-45-1 Nanakuma, Jonan-ku, Fukuoka-city, Fukuoka, Japan |

| 4LH |
|------|
| Yuichiro Eguchi |
| Saga University Hospital 5-1-1 Nabeshima, Saga-city, Saga, Japan |

| 4LF |
|------|
| Yasunori Kawaguchi, MD |
| Saga-Ken Medical Centre Koseikan 400 Kasemachi, Oaza, Nakabaru, Saga-city, Saga, Japan |

| 4LL |
|------|
| Yutaka Sasaki, MD |
| Kumamoto University Hospital 1-1-1 Honjo, Chuo-ku, Kumamoto-city, Kumamoto, |

| 4LN |
|------|
| Akio Ido, MD |
| Kagoshima University Hospital 8-35-1, Sakuragaoka, |
| Japan          | Kagoshima-city, Kagoshima, Japan |   |
|---------------|----------------------------------|---|
Supplementary Table S2. Full list of clinical trial IRBs

| Name of IRB                                                                 | Location                  |
|----------------------------------------------------------------------------|---------------------------|
| **Phase 1/2**                                                              |                           |
| Teine Keijinkai Hospital IRB                                               | Hokkaido, Japan           |
| Review Board of Human Rights and Ethics for Clinical Studies               | Tokyo, Japan              |
| Toranomon Hospital and Toranomon Hospital Kajigaya IRB                    | Tokyo, Japan              |
| Musashino Red Cross Hospital IRB                                          | Tokyo, Japan              |
| Yokohama City University Medical Center IRB                                | Kanagawa, Japan           |
| Kitasato University Hospital IRB                                           | Kanagawa, Japan           |
| Tokai University, School of Medicine IRB                                  | Kanagawa, Japan           |
| University of Yamanashi Hospital IRB                                       | Yamanashi, Japan          |
| Ogaki Municipal Hospital IRB                                               | Gifu, Japan               |
| Toyohashi Municipal Hospital IRB                                           | Aichi, Japan              |
| Mie University Hospital IRB                                                | Mie, Japan                |
| Kyoto University Hospital IRB                                              | Kyoto, Japan              |
| National Hospital Organization Kyoto Medical Center IRB                    | Kyoto, Japan              |
| Osaka Red Cross Hospital IRB                                               | Osaka, Japan              |
| Ikeda City Hospital IRB                                                    | Osaka, Japan              |
| Kaizuka City Hospital IRB                                                  | Osaka, Japan              |
| Osaka Rosai Hospital IRB                                                   | Osaka, Japan              |
| Hyogo College of Medicine Hospital IRB                                     | Hyogo, Japan              |
| Kobe City Medical Center General Hospital IRB                              | Hyogo, Japan              |
| Yasuda Hospital IRB                                                       | Tokyo, Japan              |
| Review Board of Human Rights and Ethics for Clinical Studies IRB           | Tokyo, Japan              |
| Tottori University Hospital IRB                                            | Tottori, Japan            |
| Okayama City Hospital IRB                                                  | Okayama, Japan            |
| Hiroshima University Hospital IRB                                          | Hiroshima, Japan          |
| Tokushima Prefectural Central Hospital IRB                                 | Tokushima, Japan          |
| Kagawa Prefectural Central Hospital IRB                                    | Kagawa, Japan             |
| Matsuyama Red Cross Hospital IRB                                          | Ehime, Japan              |
| Ehime University Hospital IRB                                              | Ehime, Japan              |
| Northern Kyushu Saiseikai Hospitals Combination IRB                        | Fukuoka, Japan            |
| Fukuoka University Hospital IRB                                            | Fukuoka, Japan            |
| Saga University Hospital IRB                                                | Saga, Japan               |
| Saga-Ken Medical Centre Koseikan IRB                                       | Saga, Japan               |
| Kumamoto University Hospital IRB                                           | Kumamoto, Japan           |
| Kagoshima University Hospital IRB                                          | Kagoshima, Japan          |
| **Phase 3**                                                                |                           |
| Comité Institucional de Ética de Investigación en Salud                    | Córdoba, Argentina        |
| Comité de Etica de Protocolos de Investigación                             | CABA, Argentina           |
| Committee Name                                                                 | Location                                      |
|-------------------------------------------------------------------------------|-----------------------------------------------|
| Comité Institucional de Evaluación                                           | Buenos Aires, Argentina                       |
| Comité de Revisión Institucional del Hospital Británico de Buenos Aires       | Buenos Aires, Argentina                       |
| Comité de Ética Independiente Consultorios Integrados                        | Rosario, Argentina                            |
| Royal Adelaide Hospital Human Research Ethics Committee                       | Adelaide, Australia                           |
| Sir Charles Gairdner Group Human Research Ethics Committee                    | Nedlands, Australia                           |
| Ethics Committee Medical University of Vienna                                  | Vienna, Austria                               |
| Commissie voor Medische Ethiek, Universitair Ziekenhuis Gent                 | Gent, Belgium                                 |
| Quorum Review IRB                                                             | Seattle, USA                                  |
| University Health Network Research Ethics Board                               | Toronto, Canada                               |
| Comité d'éthique chez l'humain du Centre hospitalier universitaire de Sherbrooke | Sherbrooke, Canada                            |
| Eticka komise Fakultni nemocnice Hradec Kralove                               | Hradec Kralove, Czech Republic                |
| Eticka komise Fakultni nemocnice Plzen                                       | Plzen, Czech Republic                         |
| Eticka komise Krajske zdravotni,a.s, Masarykovy nemocnice Usti nad Labem oz   | Usti nad Labem, Czech Republic                |
| CPP sud Mediterranée V - CHU de Nice – Hopital Cimiez                        | Nice, France                                  |
| Ethikkommission der Medizinischen Hochschule Hannover                         | Hannover, Germany                              |
| Egészségügyi Tudományos Tanács Klinikai Farmakológiai Etikai Bizottsága       | Budapest, Hungary                             |
| Rambam Medical Center Ethics Committee                                        | Haifa, Israel                                 |
| Sheba Medical Center Ethics Committee                                        | Ramat Gan, Israel                             |
| Galilee Medical Center Ethics Committee                                       | Nahariya, Israel                              |
| Rabin Medical Center Ethics Committee                                        | Petah-Tikva, Israel                           |
| Hadassah Medical Center Ethics Committee                                      | Jerusalem, Israel                             |
| Carmel (Lady Davis) Medical Center Ethics Committee                          | Haifa, Israel                                 |
| Kaplan Medical Center Ethics Committee                                       | Rehovot, Israel                               |
| Sourasky Medical Center Ethics Committee                                      | Tel Aviv, Israel                              |
| HaEmek Medical Center Ethics Committee                                       | Afula, Israel                                 |
| Shaare Zedek Medical Center Ethics Committee                                  | Jerusalem, Israel                             |
| Comitato Etico Indipendente dell’Azienda Ospedaliero-Universitaria di Bologna | Bologna, Italy                                |
| Comitato Etico Indipendente presso la Fondazione PTV Policlinico Tor Vergata  | Rome, Italy                                   |
| Comitato Etico dell’Azienda Provinciale per i Servizi Sanitari della         | Trento, Italy                                 |
| Provincia Autonoma di Trento                                                  |                                               |
| Comitato Etico Milano                                                         | Milano, Italy                                 |
| Comitato Etico Campania Nord                                                  | Avellino, Italy                               |
| Comitato Etico Area Vasta Nord-Ovest, Sez Autonoma del Comitato Etico Regionale | Pisa, Italy                                  |
| Comitato Etico Per Parma                  | Parma, Italy |
| Comitato Etico della Provincia Monza Brianza | Monza, Italy |
| Sez. del Comitato Etico IRCCS Istituto Tumori Giovanni Paolo II di Bari presso la Fondazione Casa Sollievo della Sofferenza | San Giovanni Rotondo, Italy |
| Comitato Etico Regionale della Liguria    | Genova, Italy |
| Comitato Etico Provinciale di Modena      | Modena, Italy |
| Comitato Etico Seconda Universita Degli Studi Di Napoli | Napoli, Italy |
| Comitato Etico Interaziendale Novara      | Novara, Italy |
| Comitato Etico Area A Milano              | Milano, Italy |
| Comitato Etico Palermo 1                  | Palermo, Italy |
| Comitato Etico dell'Universita Campus Bio-Medico di Roma | Rome, Italy |
| IRB of Pusan National University Hospital | Busan, Korea |
| IRB of Severance Hospital, Yonsei University Health System | Seoul, Korea |
| IRB of Hallym University Chuncheon Sacred Heart Hospital | Chuncheon, Korea |
| IRB of Kyungpook National University Hospital | Daegu, Korea |
| IRB of Pusan National University Yangsan Hospital | Yangsan-si, Korea |
| IRB of Gangnam Severance Hospital, Yonsei University Health System | Seoul, Korea |
| IRB of SoonChunHyang University Hospital Bucheon | Bucheon-si, Korea |
| IRB of Seoul National University Hospital Seoul National University Hospital | Seoul, Korea |
| IRB of Korea University Anam Hospital Korea University Anam Hospital | Seoul, Korea |
| Komisja Bioetyczna przy Dolnośląskiej Izbie Lekarskiej | Wroclaw, Poland |
| Comisia Nationala de Bioetica a Medicamentului si Dispozitivelor Medicale | Bucuresti, Romania |
| Ethical Council at the Ministry of Health of Russian Federation | Moscow, Russia |
| Local Ethics Committee at SBEI of HPE First Moscow State Medical University | Moscow, Russia |
| Local Ethics Committee at LLC "Medical Company "Hepatolog" | Samara, Russia |
| Local Ethics Committee at SHI of city of Moscow "City Clinical Hospital # 12 of the Moscow Healthcare Department" | Moscow, Russia |
| Central EC: Comité Etico de Investigación Clínica del Hospital Universitario y Politécnico La Fe Avenida Fernando Abril Martorell | Valencia, Spain |
| Local EC: CEIC del Hospital Puerta de Hierro Majadahonda | Madrid, Spain |
| Local EC: CEI Sevilla Sur (Hospital Universitario Virgen de Valme) | Sevilla, Spain |
| Local EC: Comité Etico de Investigación Clínica del Hospital de la Santa Creu i Sant Pau | Barcelona, Spain |
| Local EC/IRB Name | Location |
|-------------------|----------|
| Local EC: Comité Autónomo de Ética de la Investigación de Galicia | Santiago de Compostela, Spain |
| Local EC: CEIC Hospital Universitario Virgen de la Victoria | Málaga, Spain |
| Local EC: Consorcio Hospital General Universitario de Valencia - Fundación Investigación | Valenciennes, Spain |
| Local EC: CEIC Consorci Sanitari Integral | Barcelona, Spain |
| Kaohsiung Medical University Chung-Ho Memorial Hospital IRB | Kaohsiung, Taiwan |
| National Taiwan University Hospital Research Ethics Committee | Taipei, Taiwan |
| IRB of Taichung Veterans General Hospital | Taichung, Taiwan |
| IRB of Cathay General Hospital | Taipei, Taiwan |
| Office of The Khon Kaen University Ethics Committee in Human Research | Mueang Khon Kaen, Thailand |
| Siriraj IRB | Bangkok, Thailand |
| Research Ethics Committee, Faculty of Medicine, Chiang Mai University | Muang Chiang Mai, Thailand |
| The Human Research Ethics Committee of Thammasat University No. 1 (Faculty of Medicine) | Klongluang, Thailand |
| Ege Universitesi Tip Fakültesi Klinik Araştırmalar Etik Kurulu | Izmir, Turkey |
| Malatya Klinik Arastirmalar Etik Kurulu Inonu Universitesi Merkez Kampusu | Malatya, Turkey |
| Sakarya Universitesi Klinik Arastirmalar Etik Kurulu Sakarya Universitesi Tip Fakultesi Dekanligi Klinik Arastirmalar Etik Kurulu Baskanligi | Korum, Adapazari, Sakarya, Turkey |
| The Ethics Commission at Government Institution L.T.Malaya Therapy National Institute of NAMS of Ukraine | Kharkiv, Ukraine |
| The Ethics Commission at City Clinical Hospital | Vinnytsia, Ukraine |
| The Ethics Commission at Communal Healthcare Institution Kharkiv City Clinical Hospital | Kharkiv, Ukraine |
| The Ethics Commission at Kyiv City Clinical Hospital | Kyiv, Ukraine |
| The Ethics Commission at Vinnytsia M.I.Pyrogov Regional Clinical Hospital | Vinnytsia, Ukraine |
| The Ethics Commission at Poltava Regional Clinical Infectious Hospital | Poltava, Ukraine |
| NRES Committee London | London, United Kingdom |
| Quorum Review IRB | Seattle, USA |
| Howard University IRB | Washington DC, USA |
| Western IRB | Puyallup, USA |
| Baylor Scott & White Research Institute | Dallas, USA |
| Tulane University Human Research Protection Program | New Orleans, USA |
| Vanderbilt University IRB | Nashville, USA |
| UCLA Office of the Human Research Protection Program (OHRPP) | Los Angeles, USA |
| Human Subject Research Office | Miami, USA |
| Institution                                      | Location     |
|-------------------------------------------------|-------------|
| Human Subjects Protection Office/IRB            | Hershey, USA|
| Henry Ford Health Systems IRB                   | Detroit, USA|
| Committee on Clinical Investigations Beth Israel Deaconess Medical Center | Boston, USA |
| Human Studies Subcommittee IRB                   | Miami, USA  |
| VA Pittsburgh Healthcare System IRB             | Pittsburgh, USA |
| Johns Hopkins IRB                               | Baltimore, USA |
| Yale University Human Investigation Committee   | New Haven, USA |
Supplementary Table S3. Summary of platelet count levels in patients who receiving lusutrombopag and platelet transfusion in the post-marketing surveillance

| Patient number | Baseline platelet count (x10⁹/L) | Maximum platelet count (x10⁹/L) | Maximum platelet count change(x10⁹/L) |
|----------------|----------------------------------|---------------------------------|--------------------------------------|
| 1ᵃ             | 35                               | 45                              | 10                                   |
| 2              | 37                               | 53                              | 16                                   |
| 3              | 26                               | 62                              | 36                                   |

ᵃPatient 1 received a platelet transfusion but did not receive an invasive procedure.
**Supplementary Figure S1.** $C_{\text{max}}$ (A) and $\text{AUC}_{0-\tau}$ (B) in patients with Child Pugh Class A, B, and C from the phase 1/2 study.

A.

B.