Supplementary Table 1 Secondary Post-Dose Lung Function Endpoints Over Weeks 12–24 (Efficacy Estimand; Global mITT Population)

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|  | BGF MDI 320/18/9.6 µg  N=639 | GFF MDI 18/9.6 µg  N=625 | BFF MDI 320/9.6 µg  N=314 | BUD/FORM DPI 400/12 µg  N=318 |
| FEV1 AUC0–4, mL | | | | |
| n  LSM (SE) | 458  301 (9.6) | 432  284 (9.7) | 213  184 (13.4) | 223  200 (13.2) |
| *Treatment difference for BGF MDI vs. comparators* | | | | |
| LSM  95% CI  *P*-value | NA  NA  NA | 17  (–9, 42)  0.1994 | 117  (86, 148)  <0.0001 | 101  (70, 132)  <0.0001 |
| Peak change from baseline in FEV1 within 4 hours post-dosing, mL | | | | |
| n  LSM (SE) | 458  377 (9.9) | 432  359 (10.0) | 213  257 (13.8) | 223  276 (13.6) |
| *Treatment difference for BGF MDI vs. comparators* | | | | |
| LSM  95% CI  *P*-value | NA  NA  NA | 18  (–8, 44)  0.1830 | 120  (88, 152)  <0.0001 | 101  (69, 133)  <0.0001 |

Abbreviations: AUC0–4, area under the curve from 0 to 4 hours; BFF, budesonide/formoterol fumarate; BGF, budesonide/glycopyrrolate/formoterol fumarate; BUD/FORM DPI, budesonide/formoterol fumarate dry powder inhaler; CI, confidence interval; FEV1, forced expiratory volume in 1 s; GFF, glycopyrrolate/formoterol fumarate; LSM, least squares mean; MDI, metered dose inhaler; mITT, modified intent-to-treat; NA, not applicable; SE, standard error.

Supplementary Table 2 Independent Ethic Committees/Institutional Review Boards Consulted

| Independent ethics committees/institutional review boards (IRB) |
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| Showa University Hospital IRB, 158 Hatanodia, Shinagawa-KU, Tokyo, Japan  Nihonbashi EGAWA Clinic IRB, 2F Kotobuki Bld 1-1-3 Yaesu, Chuo-ku, Tokyo, Japan  Aso Iizuka Hospital IRB, 3-83, Yoshio-machi Iizuka-shi, Fukouka, Japan  Medical Corporation IHL, Shinagawa East One Medical Clinic IRB, 2-16-1 Shinagawa East One Tower 3F, Konan, Minato-ku, Tokyo, Japan  Review Board of Human Rights and Ethics for Clinical Studies IRB, 13-2 Ichiban-cho, Chiyoda-ku, Tokyo, Japan  Social Medical Corporation Keiaikai Nakagami Hospital IRB, 6-2-25 Chibana, Okinawa-Shi, Okinawa, Japan  Harasanshin General Hospital IRB, 1-8 Taihakumachi Hakata-ku, Fukouoka-shi, Japan  Medical Corporate Corporation Mitsuyakai, Maebashi Hirosegawa Clinic IRB, 2-10-9 Chiyoda-machi, Maebashi-shi, Gunma, Japan  Toyama University Hospital IRB, 2630 Sugiya Toyama-shi, Japan  Local Independent Administrative Agencies Naha City Hospital IRB, 2-31-1 Furujima, Naha-shi, Okinawa, Japan  Yaesu Sakura-dori Clinic IRB, Yaesu Center Bldg. 3F, 1-6-6 Yaesu Chuo-ku, Tokyo, Japan  Medical Corporation Association Shintokai, Yokohama Minoru Clinic IRB, 1-13-8 Bessho Minami-ku, Yokohama-shi, Kanagawa, Japan  Medical Corporation Seiwakai Nagata Hospital IRB, 523-1 Shimomiyanaga-machi, Yanagawa-shi, Fukuoka, Japan  Aida Hospital IRB, 216 Motomachi, Yabuki-machi, Nishishirakawa-gun, Fukushima, Japan  Okitama Public General Hospital IRB, 2000 Nishiotsuka, Kawanishi-machi, Higashiokitama-gun, Yamagata, Japan  Sakaide City Hospital IRB, 3-1-2 Kotobuki-cho, Sakaide-shi, Japan  IRB of International Health and Welfare Group of Kyushu District. 3-6-45 Momochihama, Sawara-ku, Fukuoka-shi, Japan  Saiseikai Toyama Hospital IRB, 33-1 Kusunoki, Toyama-shi, Toyama, Japan  Fukuoka University Hospital IRB, 7-45-1 Nanakuma, Jonan-ku, Fukuoka-shi, Japan  Kyorin University Hospital IRB, 6-20-2 Shinkawa Mitaka-shi, Tokyo, Japan  Tosei General Hospital IRB, 160 Nishioiwake-cho, Seto-shi, Aichi, Japan  IRB of Kinki University Hospital, 377-2 Onohigashi, Osakasayama-shi, Osaka, Japan  Itabashi Hospital Nihon University School of Medicine IRB, 30-1 Oyaguchi Kamicho, Itabashi-ku, Tokyo, Japan  Matasusaka City Hospital IRB, 1550 Tonomachi, Matsusaka-shi, Mie, Japan  Hamamatsu Clinical Research Network IRB, 2-12-12, Sumiyoshi Naka-ku Hamamatsu-shi Shizuoka, Japan  National Hospital Organization Disaster Medical Center IRB, 3256 Midoricho, Tachikawa-shi, Tokyo, Japan  Iwata City Hospital IRB 512-3, Okubo Iwata-shi, Shizuoka, Japan  National Hospital Organization Kinki-Chuo Chest Medical Center IRB, 1180 Nagasonecho, Kita-ku, Sakai-shi, Osaka, Japan  Tohoku University Hospital IRB, 1-1 Seiryomachi, Aoba-ku, Sendai-shi, Miyagi, Japan  IRB of Juntendo University Hospital, 3-1-3 Hongo, Bunkyo-ku, Tokyo, Japan  Medical Corporate Corporation Mitsuyakai, Maebashi Hirosegawa Clinic IRB, 2-10-9 Chiyoda-machi, Maebashi-shi, Gunam, Japan  Shizuoka City Shizuoka Hospital IRB, 10-93 Ote-machi, Aoi-ku, Shizouka-shi Shizuoka Japan  Kokkakomuinkyosaikumiairengokai Kure Kyosai Hospital IRB, 2-3-28, Nishichuo, Kure-shi, Hiroshima, Japan  Chugoku Rosai Hospital IRB, 1-5-1 Hirotagaya, Kure-shi, Hiroshima, Japan  National Hospital Organization Okinawa National Hospital IRB, 3-20-14, Ganeko, Ginowan-shi, Okinawa, Japan  Japanese Red Cross Kyoto Daini Hospital IRB, 355-5 Haruobicho, Kamanzadori-Marutamchi-agaru, Kamigyo-ku, Kyoto, Japan  IRB of Ogaki Municipal Hospital, 4-86 Minaminokawa-cho, Ogaki-shi, Gifu, Japan  Rakuwakai Otowa Hospital IRB, 2 Otowachinji-cho, Yamashina-ku, Kyoto-shi Kyoto, Japan  NTT East Tohoku Hospital IRB, 2-29-1, Yamatomachi, Wakabayashi-ku, Sendai-shi, Miyagi, Japan  Medical Coproration Fujinokikai, Hoshikuma, Dermatology Allergy Clinic IRB, 2-1-1 Noke Sawara-ku Fukuoka-shi, Fukuoka, Japan  National Hospital Organization Tenryu Hospital IRB, 4201-2 Oro, Hamakita-ku Hamamatsu, Shizuoka, Japan  Kanazawa Medical University Hospital IRB, 1-1 Daigaku, Kahoku-gun uchinadamachi, Ishikawa, Japan  Kasaoka City Hospital IRB, 5628-1 Kasaoka, Kasaoka-shi, Okayama, Japan  Shimane Prefectural Central Hospital, IRB, 4-1-1 Himehara Izumo-shi, Shimane, Japan  Saiseikai Suita Hospital IRB, 1-2 Kawazonocho, Suita-shi, Osaka, Japan  St. Luke’s International Hospital IRB, 9-1 Akashi-cho, Chuo-ku, Tokyo, Japan  Toho University Ohashi Medical Center, 2-17-6 Ohashi, Meguro-ku, Tokyo, Japan  Sekino Hospital IRB, 3-28-3 Ikebukuro, Toshima-ku, Tokyo, Japan  Nagoya University Hospital IRB, 65 Tsurumaicho, Show-ku, Nagoysa-shi, Aichi, Japan  Medical Corporation TOUKEIKAI Kitamachi Clinic IRB, 1-1-3 Kichijoji Kitamachi, Musashino-shi, Tokyo, Japan  Toyama Medical Association IRB, 336 Ninagawa, Toyama-shi, Toyama, Japan  Takeda Hospital Group IRB, 28-1 Ishidamoriminami-cho, Fushimi-ku, Kyoto-shi, Kyoto, Japan  Center Hospital of the National Center for Global Health and Medicine IRB, 1-21-1 Toyama, Shinjuku-ku, Tokyo, Japan  National Hospital Organization Tokyo National Hospital IRB, 3-1-1 Takeoka, Kiyose-shi, Tokyo, Japan  Osaka Police Hospital IRB, 10-31 Kitayama-cho, Tennouji-ku, Osaka-shi, Osaka, Japan  Kansai Medical University Hospital IRB, 2-3-1 Shinamchi, Kirakata-shi, Osaka, Japan  Shimane University Hospital IRB, 89-1 Enya-cho Izumo-shi, Shimane, Japan  Yokohama City University Hospital IRB, 3-9 Fukuura, Kanazawa-ku, Yokohama-shi, Japan  Nagoya Ekisaikai Hospital IRB, 4-66 Shonen-cho, Nakagawa-ku, Nagoya-shi, Aichi, Japan  Fujita General Hospital IRB, 14 Sanbongi, Tsukanome, Kunimi-machi, Date-gun, Fukushima, Japan  Yasuda Clinic IRB, 53 Kuzeoyabucho, Minami-ku, Kyoto-shi, Kyoto, Japan  Daido Hospital IRB, 9 Hakusui-cho, Minami-ku, Nagoya-city, Aichi, Japan  Makita Hospital IRB, 2-6-25, Shinkotoniljo, Kita-ku, Sapporo-City, Hokkaido, Japan  Kishiwada City Hospital IRB, 1001 Gakuhara-cho, Kishiwada-shi, Osaka, Japan  Takahashi Internal Medicine and Respiratory Clinic IRB, 14 Nishi 3-jo Minami 4 chome, Obihiro-shi, Hokkaido, Japan  Nakatani Hospital IRB 2501 Hosoe, Shikama-ku, Himeji-shi, Hyogo, Japan  Medical Corporation, Ouryokukai Association Nihonbashi Sakura Clinic IRB, Inamura Bldg. 5F, 1-9-2 Nihonbashi-Kayabacho, Chuo-Ku, Tokyo, Japan  Sendai Open Hospital IRB, 5-22-1 Tsurugaya, Miyagino-ku, Sendai, Miyagi, Japan  Nagaoka Red Cross Hospital IRB, 2-297-1, Sensyu, Nagaoka-shi, Niigata, Japan  Takamatsu Municipal Hospital IRB, 2-36-1 Miyawakicho, Takamatsu-shi, Kagawa, Japan  National Hospital Organization Ehime Medical Center IRB, 366 Yokogawara, Toon-shi, Ehime, Japan  National Hospital Organization Fukuoka Higashi Medical Center IRB, 1-1-1 Chidori, Koga-shi, Fukuoka, Japan |