



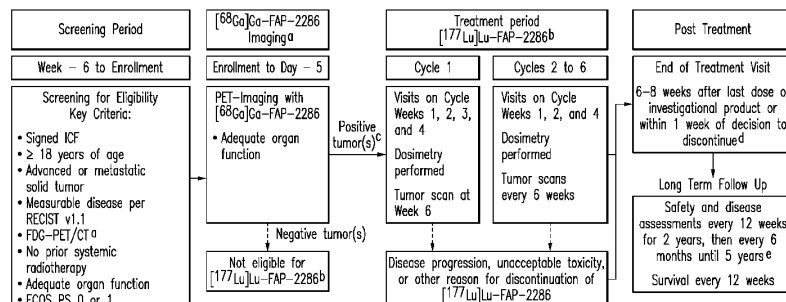
- (51) **International Patent Classification:**
A61K 51/08 (2006.01) *A61P 35/00* (2006.01)
- (21) **International Application Number:**
PCT/IB2025/051032
- (22) **International Filing Date:**
30 January 2025 (30.01.2025)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
63/627,853 01 February 2024 (01.02.2024) US
63/642,999 06 May 2024 (06.05.2024) US
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- (81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MU, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UY, UZ, VC, VN, WS, ZA, ZM, ZW.

- (84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE,

- (54) **Title:** METHODS FOR TREATING CANCER



- a. FDG-PET/CT imaging will only be performed in participants enrolled in Phase 1 and may be done at any time during screening prior to Cycle 1 Day 1. This scan does not need to be repeated if the images are available from an FDG-PET/CT scan used for baseline disease assessments required for screening.
- b. Participants who do not have FAP-positive tumors and/or do not meet entry criteria for adequate organ function will discontinue from the study and will not proceed to the treatment phase or LTFU, but will have safety assessments performed at the EOT Visit.
- c. For Phase 1, positive uptake is defined as ≥ 1.5 times higher SUVmax compared with the SUVmean of the mediastinal blood pool that is not attributable to other etiologies of tracer distribution.
- d. The EOT Visit for each participant will occur 6 to 8 weeks after the last dose of $[^{177}\text{Lu}]\text{Lu-FAP-2286}$, or within 1 week after the decision to discontinue treatment for any reason other than participant withdrawal of consent from the study or death, including withdrawal of consent for treatment, withholding the last dose of $[^{177}\text{Lu}]\text{Lu-FAP-2286}$, or not being eligible for continuation to $[^{177}\text{Lu}]\text{Lu-FAP-2286}$ therapy following administration of $[^{68}\text{Ga}]\text{Ga-FAP-2286}$.
- e. Safety assessments will be performed until death or loss to follow-up. Disease assessments should be performed until radiographic disease progression as assessed by the investigator, death, loss to follow-up, withdrawal from study, study closure, or initiation of subsequent anticancer treatments.

FIG. 1

- (57) **Abstract:** Provided herein are methods for the treatment of cancers including pancreatic cancer, lung cancer, or breast cancer comprising administering to a subject in need thereof a FAP- targeting radiotherapeutic agent either as a monotherapy or in combination with one or more chemotherapeutic agents.

[Continued on next page]

SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

- *with international search report (Art. 21(3))*
- *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*
- *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*