



- (51) **International Patent Classification:**
C12Q 1/68 (2006.01) *A61K 39/395* (2006.01)
- (21) **International Application Number:**
PCT/US2014/058437
- (22) **International Filing Date:**
30 September 2014 (30.09.2014)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/884,982 30 September 2013 (30.09.2013) US
- (71) **Applicants:** **DAIICHI SANKYO CO., LTD.** [JP/JP]; 3-5-1, Nihonbashi Honcho, Chuo-ku, Tokyo 103-8426 (JP). **U3 PHARMA GMBH** [DE/DE]; Fraunhoferstr 22, 82152 Martinsried (DE). **AMGEN, INC.** [US/US]; One Amgen Center Drive, Thousand Oaks, California 91320-1799 (US).
- (72) **Inventors:** **SCHNEIDER, Matthias**; Gartenweg 2a, 85646 Neufarn (DE). **BLUM, Sabine**; Hatzelweg 21, 81476 Parsippany (DE). **BECKMAN, Robert Allen**; 1045 Hereford Drive, Blue Bell, Pennsylvania 19422 (US). **FREEMAN, Daniel J.**; 38 Rambling Brook Drive, Holmdel, New Jersey 07733 (US). **JIN, Xiaoping**; 15 Runyon Street, Hillsborough, New Jersey 08844 (US). **MENDELL-HARARY, Renee Jeanne**; 7 Mayacoo Lakes Court, Skillman, New Jersey 08558 (US).
- (74) **Agents:** **VILLACORTA, Gilberto M.** et al.; Foley & Lardner LLP, 3000 K Street, Suite 600, Washington, DC 20007-5109 (US).

- (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, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, 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, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, 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, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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))

- (88) **Date of publication of the international search report:**
4 June 2015

(54) **Title:** NUCLEIC ACID BIOMARKER AND USE THEREOF

(57) **Abstract:** The present invention is directed to methods of identifying and treating a human subject harboring a tumor or other disease comprising assessing HRG gene expression at an mRNA level in the human subject and administering a treatment comprising an anti-HER3 antibody to the human subject whose HRG gene expression at an mRNA level is assessed as high. The present invention is also directed to methods of identifying a human subject harboring a tumor or other disease comprising assessing HRG gene expression at an mRNA level in the human subject and withholding a treatment comprising an anti-HER3 antibody to the human subject whose HRG gene expression at an mRNA level is assessed as low.

