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Safety and efficacy of JNJ-6143, a first-in-class oral AR-targeted regulated induced proximity targeting chimera at the optimal dose for further development in patients with mCRPC/mAPMR, including high-risk molecular features

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Background

JNJ-6143 (formerly HLD-0915) is a first-in-class, orally bioavailable, heterobifunctional small molecule RIPTAC™ (Regulated Induced Proximity Targeting Chimera) that selectively binds AR and BRD4 in prostate cancer (PC) cells, resulting in BRD4 loss of function and cell death. JNJ-6143 induces *in vivo* tumor regression in PC models with AR and non-AR alterations.

Methods

Multicenter phase 1 dose escalation study in patients (pts) with mCRPC/mAPMR (metastatic androgen pathway modulation-resistant) PC who progressed after ≥1 ARPI, followed by dose expansion randomizing 1:1 to 25 vs 50 mg (NCT06800313). Objectives include defining MTD, safety, PK, antitumor activity, and optimal dose for further development.

Results

As of 18MAR2026, 52 pts received JNJ-6143 orally ranging from 12.5 to 150 mg once daily. Median prior therapies were 6 (1-11): prior taxane (67%) and prior PSMA-RLT (44%). Median PSA was 102 ng/ml (6 to >5000). Treatment-related adverse events (TRAEs) in ≥15% were nausea (17%) and anemia (15%). Grade ≥3 TRAEs were observed in 5 pts (10%). There was 1 pt with DLT at 100 mg and MTD was not reached. PK exposures were comparable at doses ≥50 mg. At 50 mg (n=17), the preliminary optimal dose, TRAEs in ≥15% were all ≤ grade 2 and included nausea (4), and headache, increased cholesterol and hypertriglyceridemia (3 each); there was 1 grade ≥3 TRAE, anemia. There were no dose reductions or discontinuations for AEs. Median duration of follow up was 7.1 months (95% CI 5.8-8.7) with 14 pts continuing on treatment. Confirmed PSA50 and PSA90 were 71% and 41%, respectively, and 5/7 pts with measurable disease achieved PR (4 confirmed). PSA50 was observed in pts with high-risk features, including ARamp (6/7), AR LBDmut (2/3), AR-v7 (7/8), TP53mut/del (8/10), PTENmut/del (4/5), and RB1 mut/del (3/4).

Conclusions

JNJ-6143 is highly active in heavily pre-treated mCRPC/mAPMR pts with high-risk molecular features (ARamp/LBD, AR-v7, and tumor suppressor alterations), with an encouraging safety profile. The clinical activity, safety, and PK support 50 mg once daily as the preliminary optimal dose for further development.

Clinical trial identification

NCT06800313.

Legal entity responsible for the study

Johnson & Johnson.

Funding

Johnson & Johnson, LLC.

Disclosure

B. Garmezy: Financial Interests, Institutional, Other, Consulting: Amgen, AstraZeneca, Bayer, Bicycle Therapeutics, BioNTech, Bristol Myers Squibb, EMD Serono, Eisai, Exelixis, GSK, Immunocore, Janssen, Merck, Monte Rosa Therapeutics, Novartis, Onvivo, Pfizer, Roche – Genentech, Specialty Networks, Takeda Pharmaceuticals, Xencor; Financial Interests, Institutional, Research Grant: AbbVie, Accutar Biotechnology, Adcentrx Therapeutics, Adicet Therapeutics, Amgen, Arcus Biosciences, Arvinas, AstraZeneca, Avenzo Therapeutics, Aveo Pharmaceuticals, Bicycle Therapeutics, Bristol Myers Squibb, CRISPR Therapeutics, Daiichi Sankyo, Eikon Therapeutics, Exelixis, Roche – Genentech, Flare Therapeutics, GSK, Halda Therapeutics, Harbour BioMed, HiberCell, Ideaya Biosciences, Incyte, Janssen, Janux Therapeutics, Jubilant Therapeutics, Kineta, Kinnate BioPharma, Lilly, Loxo Oncology, Merck, Mink Therapeutics, Novartis, Nuvation Bio, Pfizer, Profound Bio, Rise Therapeutics, Rondo Therapeutics, Takeda, Teon Therapeutics, Tmunity Therapeutics, Xencor, Zenshine. 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Financial Interests, Institutional, Local PI, 11/2019 - present: Daiichi; Financial Interests, Institutional, Local PI, ending 9/2022: Eli Lilly, Tesaro; Financial Interests, Institutional, Local PI, 12/2019 - present: Epizyme; Financial Interests, Institutional, Local PI, ending 10/2023: Exelixis, GSK; Financial Interests, Institutional, Local PI, 7/2021 - present: Freenome, Samumed; Financial Interests, Institutional, Local PI, ending 10/2022: Hutchison MediPharma; Financial Interests, Institutional, Local PI, 10/2020 - present: IGM Biosciences, ImmunoGen/MarcoGenics; Financial Interests, Institutional, Local PI, ending 6/2019: Ignyta; Financial Interests, Institutional, Local PI, ending 9/2019: Incyte; Financial Interests, Institutional, Other, Subinvestigator on a sponsored clinical trial. 04/2022 - present: Jubilant; Financial Interests, Institutional, Local PI, ending 5/2008, when Millennium was purchased by Takeda: Millennium; Financial Interests, Institutional, Local PI, 10/2021 - 6/2023: Molecular Templates; Financial Interests, Institutional, Local PI, 2/2021 - present: Navire; Financial Interests, Institutional, Local PI, ending 2/2024: Novartis; Financial Interests, Institutional, Local PI, 3/2020 - 2/2024: Oncorus; Financial Interests, Institutional, Local PI, 3/2020 - present: Poseida; Financial Interests, Institutional, Local PI, 12/2019 - 2/2024: Prelude; Financial Interests, Institutional, Local PI, 12/2020 - present: PureTech, Silicon; Financial Interests, Institutional, Local PI, 06/2021 - 06/2023: Pyramid; Financial Interests, Institutional, Local PI, 3/2021 - present: RasCal; Financial Interests, Institutional, Other, Subinvestigator on a sponsored clinical trial. 12/2021 - present: Relay; Financial Interests, Institutional, Local PI, 8/2019 - present: Ribon, Turning Point; Financial Interests, Institutional, Local PI, 7/2020 - present: Sapience; Financial Interests, Institutional, Local PI, 12/2021 - present: Simcha; Financial Interests, Institutional, Other, Subinvestigator on a sponsored clinical trial. 11/2021 - present: Sirnaomics; Financial Interests, Institutional, Local PI, ending 5/2019: Syndax; Financial Interests, Institutional, Local PI, 09/2019 - 02/2024: Synthorx/Sanofi; Financial Interests, Institutional, Local PI, ending 12/2017: Taiho; Financial Interests, Institutional, Local PI, ending 7/2022: Tarveda; Financial Interests, Institutional, Local PI, 5/2021 - present. 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Roche, Sanofi Aventis, Seattle Genetics; Non-Financial Interests, Leadership Role, Vice Chair: SWOG. M.J. Morris: Financial Interests, Personal, Other, Scientific Advisory Committee: Advancelle, LinkinVax, Wren Laboratories; Financial Interests, Personal, Advisory Board: Amgen, Arvinas, AstraZeneca, BMS Celgene, Blue Earth Diagnostics, Clarity Pharmaceuticals, Curium, Daiichi, Exelixis, Flare Therapeutics, GSK, Lantheus, Molecular Partners, POINT Biopharma, Telix, Transtherabio, Z-alpha, Artbio, AbbVie; Financial Interests, Personal, Other, Scientific Advisory Board: Convergent; Financial Interests, Personal, Advisory Board, No compensation: Fusion Pharmaceuticals; Financial Interests, Personal, Stocks/Shares, 250 shares: Doximity; Financial Interests, Institutional, Coordinating PI: Novartis; Financial Interests, Institutional, Local PI: Janssen, Astellas; Financial Interests, Institutional, Trial Chair, Institutional contract: Fusion; Non-Financial Interests, Advisory Role: Bayer, Janssen Oncology, Novartis; Other, Other, Travel/lodging at conference: APCCC. A.J. Armstrong: Financial Interests, Personal, Other, Consultant: Astellas, Amgen, Precede Bio; Financial Interests, Personal, Advisory Board: Pfizer, AstraZeneca, Merck, Bayer, Janssen, Novartis, Sumitomo; Financial Interests, Institutional, Coordinating PI: Pfizer, Janssen, BMS, Bayer, Astellas, Pathos; Financial Interests, Institutional, Local PI: Merck, Amgen, Fibrogen; Financial Interests, Institutional, Steering Committee Member: AstraZeneca. J.S. de Bono: Financial Interests, Personal, Advisory Board: Amgen, Astellas, AstraZeneca, Bayer, Bioxel Therapeutics, Boehringer Ingelheim, Cellcentric, Daiichi, Eisai, Genentech Roche, Genmab, GSK, Janssen, Merck Serono, Merck Sharp & Dohme, Orion Pharma, Pfizer, Qiagen, Sanofi Aventis, Sierra Oncology, Taiho, Terumo, Vertex Pharmaceuticals, Menarini Silicon Biosystems, ImCheck Therapeutics, Crescendo, MetaCurUm, Myricx, Nurix Therapeutics, Oncternal Therapeutics, Soricimed Biopharma, AbbVie; Financial Interests, Institutional, Advisory Board: Harpoon, Dark Blue Therapeutics, Novartis, Takeda, Tango Therapeutics, SK Biopharmaceuticals Co. Ltd, Peptone Ltd, VIR Biotechnology, F. Hoffmann-La Roche Ltd, Bayer; Financial Interests, Institutional, Research Grant: Astellas, AstraZeneca, Bayer, Cellcentric, Daiichi, Genentech Roche, Genmab, GSK, Harpoon, Janssen, Merck Serono, Merck Sharp & Dohme, Orion Pharma, Pfizer, Sanofi Aventis, Sierra Oncology, Taiho, Vertex Pharmaceuticals, Crescendo Biologics, Menarini Silicon Biosystems, Immunic Therapeutics, MetaCurUm, Myricx, Nurix Therapeutics, Oncternal Therapeutics; Financial Interests, Institutional, Local PI: Amgen; Financial Interests, Institutional, Funding, Research funding to my institution: SK Biopharmaceuticals Ltd; Financial Interests, Steering Committee Member: ORIC, Amgen; Financial Interests, Local PI: Halda Therapeutics, ORIC; Non-Financial Interests, Principal Investigator: Amgen, Astellas, AstraZeneca, Bayer, Bioxel Therapeutics, Boehringer Ingelheim, Cellcentric, Daiichi, Eisai, Genentech Roche, Genmab, GSK, Harpoon, Janssen, Menarini Silicon Biosystems, Merck Serono, Merck Sharp & Dohme, Orion Pharma, Pfizer, Qiagen, Sanofi Aventis, Sierra Oncology, Taiho, Terumo, Vertex Pharmaceuticals, Crescendo, ImCheck Therapeutics, Immunic Therapeutics, Novartis, Halda Therapeutics, ORIC; Non-Financial Interests, Institutional, Product Samples: Daiichi, Bayer, Merck Serono, AstraZeneca, Harpoon, Pfizer, Sierra Oncology, Genentech/Roche, Sanofi Aventis, GSK. A. Yu: Financial Interests, Personal, Financially compensated role: Johnson & Johnson; Financial Interests, Personal, Stocks/Shares: Johnson & Johnson. K.J. Kayser-Bricker: Financial Interests, Personal, Financially compensated role: Johnson & Johnson; Financial Interests, Stocks/Shares: Johnson & Johnson. E. Attar: Financial Interests, Personal, Financially compensated role: Halda/Johnson & Johnson; Financial Interests, Personal, Stocks/Shares: Halda/Johnson & Johnson. L. Hoffman: Financial Interests, Personal, Financially compensated role: Johnson & Johnson; Financial Interests, Personal, Stocks/Shares: Johnson & Johnson. A.W. Hahn: Financial Interests, Personal, Advisory Board: Janssen, Aveo Pharmaceuticals, Exelixis, Eisai, Pfizer; Financial Interests, Personal, Invited Speaker: Intellisphere, Tolmar, Medscape, Projects in Knowledge, Curio Science, Dava Oncology, Mashup Media; Financial Interests, Institutional, Local PI: Bayer, Halda Therapeutics; Financial Interests, Institutional, Coordinating PI: Eisai. All other authors have declared no conflicts of interest.