LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad,[1] Clark Musto,[2] Shir Netanel,[3] Tian Zhang,[4] Dana E Rathkopf,[5] Marco Antonio Badillo,[6] Qiang Dong,[7] Alicia K Morgans,[8] Karie Runcie,[9] Alex Dos Santos,[10] Amitabha Bhaumik,[11] Suneel D Mundle,[10] Sharon A McCarthy,[10] Angela Lopez-Gitlitz,[12] Ashita S Batavia,[10] Daniel P Sanchez,[10] Mark Wildgust,[13] Neeraj Agarwal[14]

[1]Peter MacCallum Cancer Centre, Melbourne, Australia; [2]Janssen Research & Development, Brisbane, CA, USA; [3]Janssen Research & Development, Spring House, PA, USA; [4]University of Texas Southwestern Medical Center, Dallas, TX, USA; [5]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [6]Hospital Aranda de la Parra, Guanajuato, Mexico; [7]West China Hospital of Sichuan University, Sichuan, China; [8]Dana-Farber Cancer Institute, Boston, MA, USA; [9]New York-Presbyterian/Columbia University Medical Center, New York, NY, USA; [10]Janssen Research & Development, Raritan, NJ, USA; [11]Janssen Research & Development, Titusville, NJ, USA; [12]Janssen Research & Development, Los Angeles, CA, USA; [13]Janssen Global Services LLC, Raritan, NJ, USA; [14]University of Utah Health Hospitals and Clinics, Salt Lake City, UT, USA

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

Click anywhere to view this interactive poster

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

STUDY STATUS

- LIBERTAS is pursuing an ADT de-escalation strategy that aims to use APA alone in participants with mHSPC confirmed to have a PSA <0.2 ng/mL after 6 months of initial therapy with APA + ADT
- The LIBERTAS protocol is degendered and transgender inclusive to enable recruitment of participants in sexual and gender minority populations that are underserved and under-represented in clinical trials
- As of May 9, 2024, 15 participants representing racial and ethnic minority backgrounds and 1 SGM (sexual and gender minority) participant who self-identified as “Gay Man” have been enrolled
- The study start date was August 31, 2023. The estimated study completion date is May 31, 2027

Trial Registration

ClinicalTrials.gov Identifier: NCT05884398

ADT, androgen deprivation therapy; APA, apalutamide; mHSPC, metastatic hormone-sensitive prostate cancer; PSA, prostate-specific antigen; SGM, sexual and gender minority

NAVIGATION

STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

INTRODUCTION

- LIBERTAS is an international, open-label, randomized study that explores the use of APA + ADT as an ADT de-escalation approach in participants with mHSPC who achieve PSA <0.2 ng/mL after 6 months of initial therapy with APA + ADT
- LIBERTAS is the first phase 3 study evaluating APA + intermittent versus continuous ADT in individuals with mHSPC
- Treatment with APA + ADT resulted in rapid and deep PSA response in patients with mCSPC, with ~50% of patients attaining a PSA decline from baseline to an undetectable level (≤0.2 ng/mL) in 3 months.[1] In the TITAN phase 3 study, patients with mCSPC who achieved a PSA decline from baseline to an undetectable level (≤0.2 ng/mL), and further to ultralow levels (≤0.02 ng/mL), showed incrementally longer survival[2]

1. Chowdhury S, et al. *Ann Oncol*. 2023;34:477-485. 2. Merseburger A, et al. European Society for Medical Oncology Congress 2023; October 20-24, 2023; Madrid, Spain.
ADT, androgen deprivation therapy; APA, apalutamide; mCSPC, metastatic castration- sensitive prostate cancer; metastatic hormone-sensitive prostate cancer; mHSPC; metastatic hormone-sensitive prostate cancer; PSA, prostrate-specific antigen

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

NAVIGATION

STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

INTRODUCTION

- ADT is associated with adverse events and decreased QoL in individuals with advanced prostate cancer, including cognitive decline, metabolic disturbance, and sleep disturbance.[3,4] Therefore, ADT de-escalation in combination with an androgen receptor pathway inhibitor is highly desirable to reduce the ADT side effect burden without loss of efficacy. However, treatment recommendations on the use of an ADT de-escalation approach are limited
- Historically, mHSPC has been studied almost exclusively in cisgender men. In a patient voice exercise gathering feedback from a focus group of patients with mHSPC and caregivers on their experiences with mHSPC and on the proposed study design, a key takeaway was the disparity of treatment faced by gender-diverse individuals. There is an unmet need to understand and address the prostate cancer-related disease risks for transgender women[5,6]

NAVIGATION

STUDY STATUS
INTRODUCTION 2
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

3. Perera M, et al. *Nat Rev Urol*. 2020;17:469-481. 4. Tucci M, et al. *Minerva Urol Nefrol*. 2018;70:144-151. 5. Loria M, et al. *Prostate Cancer Prostatic Dis*. Feb 7, 2024, online ahead of print. 6. Nik-Ahd F, et al. *JAMA*. 2023;329:1877-1879.
ADT, androgen deprivation therapy; APA, apalutamide; mHSPC, metastatic hormone-sensitive prostate cancer; QoL, quality of life

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

INTRODUCTION

- ADT is an important therapeutic component of gender-affirming care (GAC) for transgender women who are medically transitioning. With inclusion of transgender individuals who may be receiving GAC, reducing ADT must be approached with deliberate care
- LIBERTAS is the first degendered and transgender-inclusive prostate cancer study
- Consistent with the FDA Diversity Plan to improve enrollment of participants from under-represented racial and ethnic populations in clinical trials,[7] LIBERTAS uses broad eligibility criteria to allow inclusion of individuals under-represented in clinical trials, including Black and African American participants, transgender, nonbinary, and gender-diverse participants, and participants with disabilities, as well as patients showing metastases on PSMA PET scan only

7. Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry. 2022. https://regulations.gov. Accessed March 31, 2024.
FDA, Food and Drug Administration; PSMA PET, prostate-specific membrane antigen positron emission tomography

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

NAVIGATION

STUDY STATUS
INTRODUCTION 3
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

OBJECTIVE

- The overall objective of the LIBERTAS study is to evaluate whether APA + intermittent ADT in participants with mHSPC who achieved PSA <0.2 ng/mL after 6 months of initial therapy with APA + ADT provides noninferior rPFS and reduces hot flash burden compared with APA + continuous ADT
  - A cohort of participants undergoing GAC will also be evaluated

ADT, androgen deprivation therapy; APA, apalutamide; GAC, gender-affirming care; mHSPC, metastatic hormone-sensitive prostate cancer; PSA, prostrate-specific antigen; rPFS, radiographic progression-free survival

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

NAVIGATION

STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

METHODS

- Gender-specific language was removed from the LIBERTAS study protocol (Table 1)
- Study site staff are offered healthcare-specific sexual and gender minority cultural sensitivity training
- SOGI (sexual orientation and gender identity) data are collected and reported in the United States
- Eligible participants have metastatic prostate cancer documented by conventional imaging (CT, MRI, or bone scan) and/or next-generation imaging (NGI)
- An independent data monitoring committee will conduct periodic review of safety data

CT, computed tomography; MRI, magnetic resonance imaging

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

NAVIGATION

STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

METHODS

Examples for de-gendering protocol and clinical study language

De-gendering language
[male] [or] [female] assigned at birth (if any sex is eligible, or if the diagnosis defines the patient population already, this criterion should not be used at all)
Colorectal cancer, acute myeloid leukemia: in most cases, any sex is eligible (no need for criterion); in rare cases, the trial is specific for sex, in which case the team should word as needed to ensure inclusion of intersex and transgender persons
Breast, ovarian, uterine, or prostate cancer: either any sex is eligible (no need for criterion) or the trial is specific for sex, in which case the team should word as needed to ensure inclusion of intersex and transgender persons. If the trial is studying a specific population (eg, lung cancer in "females") use "Female Assigned at Birth, inclusive of all gender identities"
Study in pregnancy: use "participants" instead of "pregnant women" throughout protocol, inclusion/exclusion criteria
X-linked or Y-linked diseases: specify male or female as "assigned at birth" whenever male/female is used in protocol. Use "XX, XY chromosomes" if genetic screening is involved in study

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

NAVIGATION

STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

METHODS

Examples for de-gendering protocol and clinical study language

Contraceptive language
Search document for all binary gender references using the following terms: female, male, man, woman, men, women, and replace with “persons” or “individuals” or “participants” instead of “males/females” — in most cases “participant” will be the preferred alternative
Search document for all binary gender references using the following terms: “he,” “she,” “him,” “her,” “his,” “hers,” and replace with “they” or “their(s)”
Terms such as “father” or “mother” can be replaced with “biological parent”
Example: • A participant must agree not to ~~father a child~~ impregnate a partner via their semen while enrolled in this study • ~~[Male or female] Penile or vaginal~~ An external or internal condom with or without spermicide

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

NAVIGATION

STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

METHODS

Examples for de-gendering protocol and clinical study language

Sexual orientation
Review any language assumptions around binary sexuality, as some participants may not be engaging in sexual activities with partners where pregnancy has relevancy
Example: *Sexual abstinence is considered a highly effective method only if defined as refraining from ~~heterosexual~~ sexual intercourse where pregnancy could occur during the entire period of risk associated with the study treatment*

NAVIGATION

STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual Orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

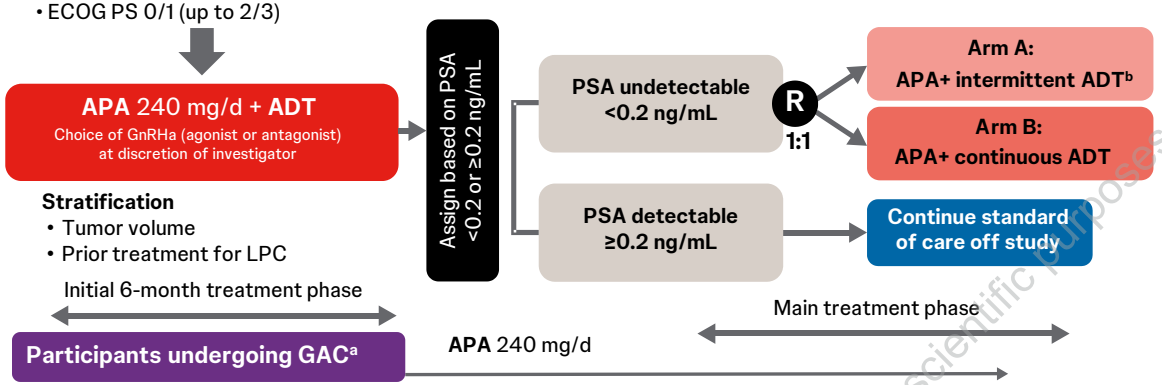
Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

METHODS

LIBERTAS study design. Participants undergoing medical or surgical GAC will be evaluated as a separate cohort



[a]Participants undergoing GAC or with a variation in physical development who receive exogenous hormones will be evaluated as a separate cohort with regard to their outcomes in a more descriptive manner. These participants will not be randomized for the main treatment phase and will be continuously treated with APA from study initiation until disease progression. Participants receiving GAC or with a variation in physical development who receive exogenous hormones will continue that throughout the study

[b]ADT can be restarted in the APA + intermittent ADT group for participants with new or worsening cancer symptoms, PSA increase to >10 ng/mL (or return to baseline level when PSA was <10 ng/mL before start of ADT), or PSA doubling time <6 months

[c]Conventional imaging (CT/MRI and 99mTc bone scans) will be used for the assessment of the primary and secondary end points

[d]Algorithmically developed end points from digital health tools measuring hot flash burden, sleep, activity, and neurocognitive function

Coprimary end points

rPFS at 18 months from randomization
• Radiographic progression assessed using conventional imaging[c]

Hot flash severity score and hot flash frequency at 18 months from randomization
• Hot flashes will be evaluated using the Hot Flash Related Daily Interference Scale PRO Questionnaire

Key secondary end points

- Mean daily changes in hot flash severity score from baseline to all postrandomization visits
- PFS2
- OS and cancer-specific survival
- PSA outcomes
- Duration of time on ADT
- Duration of time with testosterone <50 ng/dL
- Time to recovery of testosterone >50 ng/dL
- Time to mCRPC
- Safety
- PROs, QoL, hot flash–related QoL[d]
- Treatment effect on activity, sleep, and neurocognition as measured via digital health tools

ADT, androgen deprivation therapy; APA, apalutamide; CT, computerized tomography; ECOG PS, Eastern Cooperative Oncology Group performance status; GAC, gender-affirming care; GnRHa, gonadotropin-releasing hormone agonist or antagonist; LPC, localized prostate cancer; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; MRI, magnetic resonance imaging; OS, overall survival; PFS2, second progression-free survival; PRO, patient-reported outcome, PSA, prostrate-specific antigen; QoL, quality of life; R, randomization; rPFS, radiographic progression-free survival

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

NAVIGATION
STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

METHODS

- **Key inclusion criteria**
  - Metastatic prostate cancer, inclusive of all gender identities
  - Metastasis detected by conventional imaging as well as NGI such as PSMA PET
  - ≤3 months of ADT prior to enrollment except for participants receiving ADT as part of their GAC
- For a complete list of criteria, see https://clinicaltrials.gov/study/NCT05884398
- **Key exclusion criteria**
  - Prior bilateral orchiectomy, with the exception of participants who completed this procedure as GAC without progressive prostate cancer thereafter in order to be considered as mHSPC
  - For LPC or locally advanced prostate cancer, participants must have received ≤3 years total of ADT and all other forms of prior systemic therapies for prostate cancer and all such therapies completed ≥1 year prior to the first dose of APA (except for participants who receive ADT as part of their GAC)

ADT, androgen deprivation therapy; APA, apalutamide; GAC, gender-affirming care; LPC, localized prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; NGI, next-generation imaging; PSMA PET, prostate-specific membrane antigen positron emission tomography

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

NAVIGATION

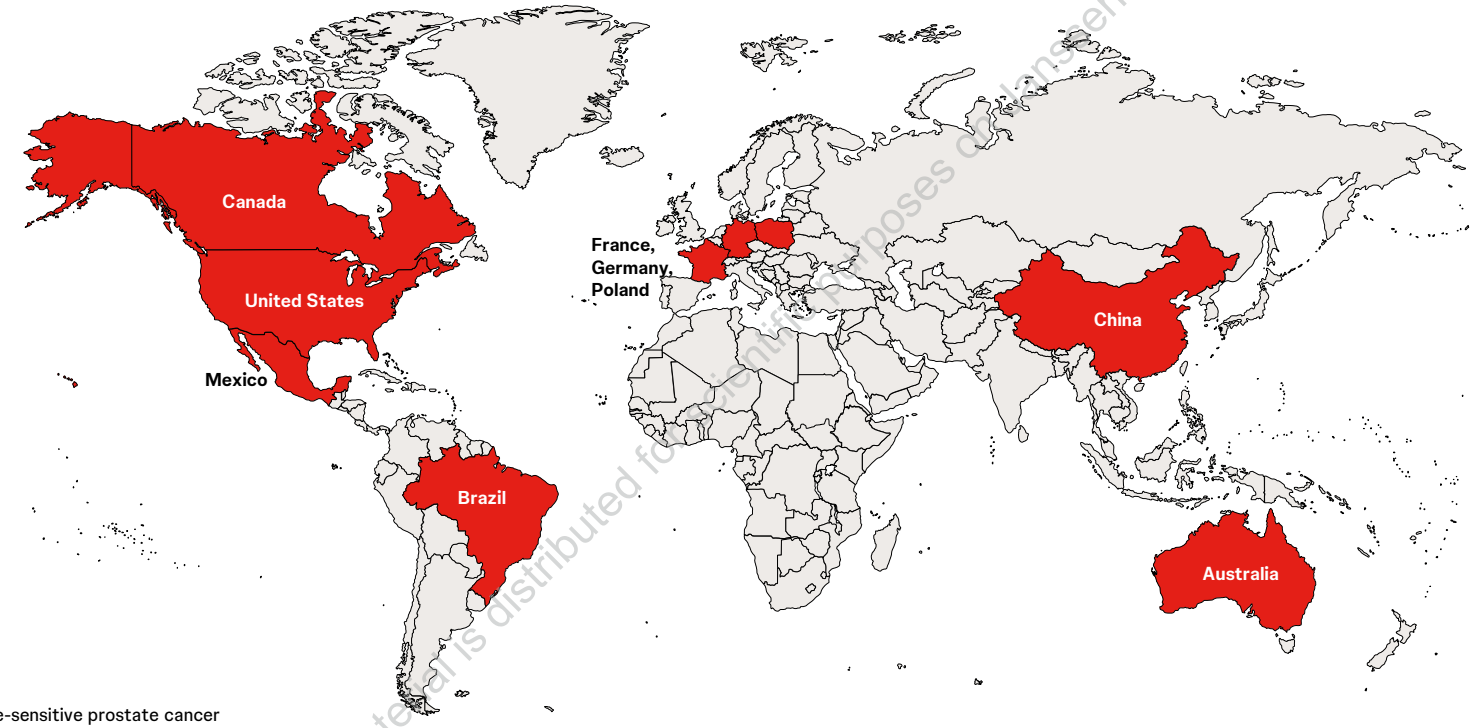
STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

METHODS

LIBERTAS is enrolling approximately 333 participants with mHSPC, inclusive of all gender identities, over 2 years at 86 sites across 9 countries



mHSPC, metastatic hormone-sensitive prostate cancer

Presented by: A Azad at the 2024 ASCO Annual Meeting; May 31 – June 4, 2024; Chicago, IL, USA

NAVIGATION

STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS
Study eligibility criteria
LIBERTAS
Participating countries
APPENDIX

LIBERTAS, a Degendered and Transgender-Inclusive Phase 3 Study of Apalutamide Plus Intermittent Versus Continuous Androgen Deprivation Therapy in Participants With Metastatic Hormone-Sensitive Prostate Cancer

Arun Azad, Clark Musto, Shir Netanel, Tian Zhang, Dana E Rathkopf, Marco Antonio Badillo, Qiang Dong, Alicia K Morgans, Karie Runcie, Alex Dos Santos, Amitabha Bhaumik, Suneel D Mundle, Sharon A McCarthy, Angela Lopez-Gitlitz, Ashita S Batavia, Daniel P Sanchez, Mark Wildgust, Neeraj Agarwal

APPENDIX

REFERENCES:

1. Chowdhury S, et al. *Ann Oncol*. 2023;34:477-485.
2. Merseburger A, et al. European Society for Medical Oncology Congress 2023; October 20-24, 2023; Madrid, Spain.
3. Perera M, et al. *Nat Rev Urol*. 2020;17:469-481.
4. Tucci M, et al. *Minerva Urol Nefrol*. 2018;70:144-151.
5. Loria M, et al. *Prostate Cancer Prostatic Dis*. Feb 7, 2024, online ahead of print.
6. Nik-Ahd F, et al. *JAMA*. 2023;329:1877-1879.
7. Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry. 2022. https://regulations.gov. Accessed March 31, 2024.

DISCLOSURES:

AA: Aculeus Therapeutics, Amgen, Astellas, AstraZeneca, Bayer, Bristol Myers Squibb, Daiichi Sankyo, Ipsen, Janssen, Merck Serono, Merck Sharp & Dohme, Novartis, Noxopharm, Pfizer, Sanofi, Telix Pharmaceuticals, Tolmar.

ACKNOWLEDGMENTS:

The authors thank the following individuals for their contributions: Sean Cahill, Vicky Cárdenas, Keith Crawford, Peter De Porre, Earl Fowlkes, Eli Green, Alyson Gregg, Neelum Jeste, Alex Keuroghlian, Debra Mitchell, Sean Murphy, Robert Patrizi, Joël Pointon, Scout, Joe Trombello, Jennifer Whalen.
Writing assistance was provided by Ann Tighe, PhD, of Parexel.
The study was sponsored by Janssen Research & Development, LLC, a Johnson & Johnson company.

NAVIGATION

STUDY STATUS
INTRODUCTION 1
OBJECTIVE
METHODS
De-gendering language
Contraceptive language
Sexual orientation
LIBERTAS study design
LIBERTAS Study eligibility criteria
LIBERTAS Participating countries
APPENDIX