5. STUDY SYNOPSIS

Protocol title:	A phase II randomized, open-label study comparing salvage radiotherapy in combination with 6 months of androgen-deprivation therapy (ADT) with LHRH agonist or antagonist versus anti-androgen therapy (AAT) with apalutamide in patients with biochemical progression after radical prostatectomy.
Short title/acronym:	SAVE
Protocol number:	CTOR18001GZA
Eudract number:	2018-004365-13
Sponsor:	GZA vzw Oosterveldlaan 22, 2610 Wilrijk, Belgium
Study responsible physician:	Dr. Piet Dirix
Investigator(s)/study center(s):	Dr. Piet Ost – UZ Gent Dr. Nick Liefhooghe - AZ Groeninge
Study design:	Open-label, randomized, phase II.
Planned sample size:	202
Purpose of trial:	To evaluate AAT with apalutamide as a sexual function-sparing alternative to ADT with LHRH agonist or antagonist.
Primary objective:	To compare EPIC-26 sexual function at 9 months.
Secondary objective(s):	1. To assess general quality of life. 2. To evaluate safety. 3. To evaluate efficacy.
Medical condition under investigation:	Prostate cancer patients with biochemical progression after radical prostatectomy and planned for salvage radiotherapy.
Participant selection criteria (summary):	Prostate cancer patients with biochemical progression (PSA detectable with confirmed rise, at least 2 weeks apart) at least 8 weeks after radical prostatectomy and without severe erectile dysfunction according to IIEF-5 questionnaire who are planned for salvage radiotherapy.
Treatment:	Apalutamide 240mg (JNJ-56021927)
Duration of treatment:	6 months
Version & date of protocol:	Version 5.0 21/04/2020
Version & date of protocol amendments:	Amendment 4 21/04/2020
Trial registration:	This study is registered on www.clinicaltrials.gov

Financial support as well as study drug is provided by Janssen Pharmaceutica N.V.

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