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1647TiP **Antiandrogen therapy and TMPRSS2 status: How prostate cancer patients are protected from COVID-19 pandemic**

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Background: The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) enters into target cells by exploiting the cellular transmembrane protease serine 2 (TMPRSS2) for spike protein cleavage. Male gender, age, obesity, diabetes, hypertension are some of the factors related to coronavirus disease 2019 (COVID-19) severity and mortality. Prostate cancer (PCa) patients (pts) are expected to be at higher risk for COVID-19 due to age and disease related comorbidities. TMPRSS2 transcription depends on androgens and androgen receptor and it is significantly downregulated by hormone therapies commonly used to treat PCa in different settings. Supposing that in PCa pts androgen deprivation therapy (ADT) could hamper SARS-CoV-2 cell entry, we aim to evaluate if the presence of single nucleotide

polymorphisms (SNPs) in the androgen responsive elements (AREs) in the TMPRSS2 promoter is associated to COVID-19 outcomes.

Trial design: The present exploratory biological study is part of an ongoing retrospective-prospective multicenter cohort trial designed to verify whether PCa pts on ADT develop milder clinical presentation of COVID-19 than the general male population. The cohort trial collects real world data since February 2020 through regional databases that identified 200,000 potential pts to be enrolled to compare the clinical outcome of COVID-19 between PCa pts on active therapy (Study Group) and non-PCa pts (Control Group). Within the Study Group, we will compare the COVID-19 outcome between treatment subgroups: ADT alone, ADT plus antiandrogens, CYP17 inhibitors or chemotherapy. To identify SNPs in AREs of the TMPRSS2 gene and to describe possible associations with COVID-19 outcome, blood samples will be collected from 50 PCa pts treated at selected centers. Pts will participate voluntarily and sign an informed consent approved by local ethical committees. We will centrally perform PBMCs isolation and DNA extraction by using qiagen QIAamp DNA Mini Kit. SNPs will be evaluated with the Axiom™ Human Genotyping SARS-CoV-2 array. The effect of ADT will be corrected depending on identified SNPs and associated to COVID-19 outcome. The study is ongoing: we processed blood samples from 21 pts. Final results are awaited by the end of 2021.

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