Clinical Trial Summary

IPASS: A Study on the Tolerability and Effectiveness of Injectable Testosterone Undecanoate for the Treatment of Male Hypogonadism in a Worldwide Sample of 1,438 Men

Zitzmann M, et al. Journal of Sexual Medicine 2013; 10: 579–588

What is the clinical paper about?

- The focus of this study was to confirm the safety and effectiveness of Bayer's injectable long-acting testosterone undecanoate (TU) (Nebido®/Reandron®)in hypogonadal men in daily clinical practice, in a large, worldwide cohort.
- The main outcome measures assessed were: erectile function, libido, vigour/vitality, mood, and ability to concentrate (all assessed by physician interview using items and five-point Likert scales), physical and circulatory parameters, haematocrit and prostate-specific antigen (PSA) levels, glucose control, and lipid profiles.

What is the methodology?

- This was an international, multi-centre, 23-country, post-authorisation, single-arm, prospective observational study conducted in men with primary or secondary hypogonadism or late-onset hypogonadism.
- Patients (n = 1,438; mean age: 49.2 ± 13.9 years), including those previously treated with other forms of testosterone and those who were treatment-naïve, each received ≤5 TU injections during a 9 to 12-month observation period.
- At the end of the observational period, patients rated treatment satisfaction, overall tolerability, and effectiveness of the treatment compared with previous androgen therapies (if applicable).

What are the key results?

- **Efficacy:** Scores for vigour (proportion of patients with very low/low at baseline vs injection 5: 52% vs 8%), general mood (36% vs 5%), and ability to concentrate (35% vs 5%), improved throughout the study.
- After four TU injection intervals, the percentage of patients with low/very low levels of sexual desire/libido decreased from 64% at baseline to 10%.
- Mean waist circumference decreased from 100 to 96 cm.
- Blood pressure and lipid parameters improved significantly during treatment.
- At the last observation, 89% of patients were satisfied or very satisfied with TU therapy.
- **Safety:** Adverse events and adverse drug reactions (ADRs) occurred in 12% and 6% of patients, respectively, mostly mild to moderate.
- The most common ADRs were increase in haematocrit, increase in PSA, and injection-site pain (all <1%).
- No case of prostate cancer was observed.

What are the key conclusions?

- Use of injectable long-acting TU therapy in hypogonadal men was effective and well-tolerated in daily clinical practice in a worldwide setting.
- Clinically relevant efficacy was reported, especially regarding sexual function.
- TU was safe and well-tolerated in patients with male hypogonadism; abnormal increases in haematocrit and PSA were observed but were infrequent.
- **However**, this report suffers from the limitations common to all observational studies, such as the possibility of inconsistent and incomplete reporting of data and the inclusion of heterogenous patient populations and local practice that could bias the findings.