

Italian pharmaceutical R&D excellence at the
33rd Congress of the European Association of Urology
Efficacy and tolerability results with Oncofid®P-B
in patients with papillary bladder cancer

- No new drug treatments for primary or recurrent papillary bladder cancer in 15 years
- Oncofid®P-B is a Paclitaxel-Hyaluronan Bioconjugate developed and patented by Fidia farmaceutici, a leading Italian pharmaceutical multinational company

Copenhagen, March 18, 2018 – Fidia farmaceutici today announced the positive results from a phase II trial evaluating efficacy and tolerability of Oncofid®P-B, an innovative Paclitaxel-Hyaluronan Bioconjugate targeted to cancer cells, in patients with primary or recurrent Ta G1-G2 papillary bladder cancer.

The multicenter, open-label, non-randomized, international study evaluated 600mg Oncofid®P-B administered in 6 weekly intravesical instillations, followed by a 6+6-month maintenance phase, in 60 patients with papillary bladder cancer.

Rate of complete response (CR) was 45,0% (27 CR/60 patients), with excellent safety and tolerability. A higher CR rate (57,1% - 16/28 patients) was observed in the subgroup of patients who had not previously been treated with chemo- or immunotherapy.

Only one adverse event (urinary tract infection) was treatment-related and resolved in 5 days with antibiotic therapy. No patient suspended treatment for occurrence or severity of adverse events.

Bladder carcinoma is the 5th most common malignant disease in Western countries, the 2nd most prevalent urologic cancer after prostate cancer in men ¹. Approximately 75-85% of patients present with a disease confined to the mucosa or submucosa (non-muscle invasive bladder carcinoma – NMIBC)^{2,3}.

Standard of care for papillary NMIBC includes transurethral resection (TURBT), followed by intravesical instillation with chemo- (mitomycin C) or immunotherapy (Bacillus Calmette-Guérin - BCG) to prevent recurrences⁴ (30%-60% rate).

*“People with a diagnosis of papillary bladder cancer are still in need of alternative treatment options with favorable risk/benefit and tolerability profiles, and fewer complications than current standard care based on mitomycin C and BCG after TURBT - said **Prof. PierFrancesco Bassi**, Principal Investigator - These clinically relevant results support the potential of Oncofid as an innovative option that adds significantly to our therapeutic armamentarium, with important benefits for patients, in terms of efficacy, safety and quality of life.”*

¹ Cumberbatch MG, Rota M, Catto JW, La Vecchia C The Role of Tobacco Smoke in Bladder and Kidney Carcinogenesis: A Comparison of Exposures and Meta-analysis of Incidence and Mortality Risks. Eur Urol. 2016;70(3):458-66.

² Smith, A. B. et al. Muscle-invasive bladder cancer: evaluating treatment and survival in the National Cancer Data Base. BJU Int. 2014; 719–26.

³ Burger, M. et al. Epidemiology and risk factors of urothelial bladder cancer. Eur. Urol. 2013; 63:234–41.

⁴ J.A. Witjes, et al. Guidelines on Muscle-invasive and Metastatic Bladder Cancer. European Association of Urology. 2015



*“Our excitement with the clinical development of Oncofid continues to grow - said **Dr. Carlo Pizzocaro**, President and CEO of Fidia farmaceutici - Several decades of R&D and know-how on hyaluronic acid have enabled Fidia to develop a proprietary platform that combines hyaluronic acid with pharmacologically active ingredients, offering a unique therapeutic approach based on a novel mechanism of action. Once again, Italian excellence in R&D is underpinning ambitious global projects, in collaboration with national and international centers of excellence.”*

Fidia farmaceutici

Fidia farmaceutici is part of Fidia Pharma Group, an Italian multinational company, with R&D, manufacturing and sales capabilities, and an extensive product portfolio mainly based on natural and functionalized hyaluronic acid (over 650 patents), in joint care, wound healing, ophthalmology, aesthetics and regenerative medicine. Manufacturing operations are FDA-inspected and approved, and the company extends its global reach through wholly-owned subsidiaries and partners in 100 countries worldwide.