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Improvement in QoL and Reduction in LVP Requirement from the MOSAIC Study: A Multicenter, Open-Label, Prospective 3-Month Study of the Alfapump System in Refractory Ascites

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Background: The Alfapump system (Sequana Medical AG) is a completely implantable and rechargeable subcutaneous pump that automatically moves ascites to the bladder. We present 3-month (3M) efficacy and safety data from the MOSAIC study wherein cirrhotic patients with refractory ascites in North America underwent Alfapump placement (clinicaltrials.gov #NCT02400164).

Method: Prospective, open-label, single-arm, multicenter study, enrolling 30 patients with refractory ascites not eligible for TIPS. Efficacy is reported as LVP requirement and QoL by Chronic Liver Disease Questionnaire (CLDQ) and AscitesQ (a validated Mayo Clinic tool). Safety at 3-24 months is reported as incidence and severity of device- and procedure-related serious adverse events and overall survival (OS).

Results: Of 30 patients implanted (median 63y, (32-72); M:F 17:13; MELD 15.1 (SD 5.1); alcoholic etiology n=14), 29 had Alfapumps percutaneously implanted by interventional radiologists; 27 reached the 3M follow-up period; 2 systems were explanted (Abd. wall cellulitis, both fully recovered); and 1 death occurred (unrelated ESLD). Median study follow-up was 9.3M (1.1-16.9), on treatment 8.8M (0.9-16.7). Compared with baseline (BL), mean 3M QoL improved in both CLDQ (3.88 vs 4.88 [BL, 3M]; $p<0.05$) and AscitesQ (51.7 vs 32.2 [BL, 3M]; $p<0.05$). OS at 3M was 96.7% (SD 3.3) and 88.3% (SD 6.4) at 12M. Mean OS was estimated at 15.1M (SD 0.8). Only 9 patients (30%) required subsequent LVP (19 events, mean 2.2/Pt) incl. 5 events in 2 patients due to catheter blockage and 11 events in 5 patients due to insufficient pumped volume. Re-interventions occurred in 4 patients; 3 due to leaking, kinked, or blocked peritoneal catheters, and 1 due to a pump malfunction (exchanged during initial implant procedure). All fully recovered.

Safety events included: 11 renal dysfunction events in 8 patients (9 resolved or resolved w. sequelae, 1 resolving & 1 unresolved) including 6 Acute Kidney

Injury (AKI) events in 4 patients (all resolved or resolved w. sequelae); and 24 infections in 14 patients incl. 1 SBP (despite antibiotic prophylaxis) & 6 urinary tract infections (all resolved).

Conclusions: Alfapump implantation resulted in a clinically significant improvement in mean QoL, as measured by CLDQ and AscitesQ and elimination of LVP requirement in 70% of patients at 3M. Study patients had greater than expected OS compared with prior publications. Re-interventions, explants, and adverse events related to AKI and infection remain as concerns. Further studies should include revised catheter design and procedural and post-procedure care algorithms.

Character count:

2633 incl. spaces excl. title and authors.

Title = 177 incl. spaces (limit 255)

Authors = 336 (may need to be included with overall limit)

TOTAL = 2970 excl. Title (Overall limit = 2,700)