THE ARGUS® II – A 60 ELECTRODE NEURAL INTERFACE

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Methods: All subjects were implanted with a Second Sight Medical Products, Inc. Argus® II implant and had bare light perception or worse due to Retinitis Pigmentosa (clinicaltrials.gov NCT00407602). Visual function was evaluated by grating visual acuity, assessing the ability to determine the direction of motion of a line and the location of a square on an LCD screen, letter reading, and orientation and mobility tests.

Results: 30 subjects have been implanted at 10 centers and all used the system at home. In the O&M tests, subjects were able to successfully navigate to the door and to the end of the line more often with the System ON vs. OFF. At the most recent follow-up visits, 96% (26/27) of subjects show a significant improvement in accuracy with the system ON compared with OFF ($p<0.05$, Student's t-test) in the square localization test, and 57% (16/28) perform Direction of Motion tests better with the System ON vs. OFF. Thirty-three percent (33%) of subjects in the most recent Argus II cohort (5/15) have statistically measurable grating visual acuity better than 2.9 logMAR (Snellen 20/15900) with System ON in their implanted eye, and the best subject measured 1.8 logMAR (20/1260). Subjects were able to correctly identify letters in a closed set 74% of the time with the System ON vs. 17% with the System OFF (n=24 subjects).

Conclusions: With up to 2.7 years follow-up on 30 subjects, this is the largest and longest study of a visual prosthesis to date. The results confirm previous reports on the ability of the Argus prosthesis to provide visual function over the long-term. This is further validation for the Argus platform's high reliability. The Argus II has received CE Mark and is now commercially available in Europe.