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Comparison of Quality of Life Responses From Caregiver and Children Aged ≥ 7 Years Using the Quality of Life in Short Stature Youth (QoLISSY) Questionnaire, Following 12 Months of Growth Hormone Treatment With Either a Weekly Somatrogen or a Daily Genotropin Injection Schedule

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STEP 6: ABSTRACT BODY:

QoLISSY abstract for ENDO March 2021 **AUTHORS & AFFILIATIONS:** J Loftus, J Quitmann, S Valluri, A Pastrak, L Reiter, CL Roland **TITLE:** Comparison of quality of life responses from Caregiver and Children aged ≥ 7 years using the Quality of Life in Short Stature Youth (QoLISSY) questionnaire, following 12 months of growth hormone treatment with either a weekly Somatrogen or a daily Genotropin injection schedule.

OBJECTIVE: Paediatric growth hormone deficiency (pGHD) affects 1/4,000 children. Treatment with daily sub-cutaneous injections of recombinant human growth hormone (r-hGH) increase height velocity and quality of life (QoL). A recent randomised controlled clinical trial (NCT02968004) evaluated the efficacy/safety of weekly Somatrogen (hGH-CTP) and daily Genotropin in pGHD. QoL (an exploratory endpoint) was evaluated using the validated Quality of Life in Short Stature Youth (QoLISSY) questionnaire, which includes three subscales (physical, social, emotional) and total score.

METHODS: The QoLISSY core module was administered to patients (aged 3-11 years [girls], 3-12 years [boys]) and parents in US, UK, Australia, New Zealand, Belarus, Russia, Ukraine and Spain, at Baseline (BL) and 12 months after treatment start. The QoLISSY-CHILD was completed by children aged ≥ 7 years; QoLISSY-PARENT was completed by the Caregiver for children < 7 years, and for some children aged ≥ 7 years. We report here only the QoLISSY results for children aged ≥ 7 years (reported from either child or parent).

RESULTS: For Total QoLISSY-PARENT, for children aged ≥ 7 years in the Somatrogen group (N=26), mean scores are 53.65 (BL) and 65.52 (month 12) with mean change of 13.01 (95% Confidence Interval [CI]: 3.99, 22.02). In the Genotropin group (N=28), mean scores are 55.89 (BL) and 63.66 (month 12) with mean change of 6.60 (CI: -0.21, 13.40). For Total QoLISSY-CHILD in the Somatrogen group (N=35), mean scores are 61.48 (BL) and 74.69 (month 12) with mean change of 13.00 (CI: 5.81, 20.19). In the Genotropin group (N=35), these scores are 60.96 (BL) and 69.03 (Month 12) with mean change of 7.84 (CI: 2.71, 12.97). Scores of > 70 indicate a good QoL.

CONCLUSIONS: QoL in children aged ≥ 7 years improved, following 12 months of either treatment, whether this was reported by caregiver or child. However, these data show that the baseline scores and 12 month scores from the QoLISSY-PARENT in both treatment groups were numerically lower than those reported by the child. This is consistent with the literature¹, in which the caregivers generally report lower QoL scores on behalf of the child.

¹Explaining parent-child (dis)agreement in generic and short stature-specific health-related quality of life reports: do family and social relationships matter? Quitmann et al *Health and Quality of Life Outcomes* 2016 vol 14, Article 150

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Author Disclosure Information:

J. Loftus: Employee; Self; Pfizer, Inc.. Stock Owner; Self; Pfizer, Inc.. **J. Quitmann:** None. **S. Valluri:** Employee; Self; Pfizer, Inc.. Stock Owner; Self; Pfizer, Inc. **A. Pastrak:** Employee; Self; OPKO. Stock Owner; Self; OPKO. **L. Reiter:** Employee; Self; OPKO. Stock Owner; Self; OPKO. **C. Roland:** Employee; Self; Pfizer, Inc.. Stock Owner; Self; Pfizer, Inc..

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