

WELCOME TO RLS GLOBAL NEWSLETTER No. 10, 2020

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It is time to summarize a very different but interesting year, 2020.

2020 is the year when ChloraSolv was awarded on the first tenders in Sweden. The response and feedback have overall been very positive from the regions and the municipalities. The clinicians confirm the effect of the technology as well as the need of a more gentle method to support debridement. During the year the first commercial footprint was also established in Denmark and UK.

Today, most of the customer interactions are virtual due to the pandemic. RLS has arranged several webinars with relevant topics to drive the awareness about good debridement and ChloraSolv. RLS has close communication with most of the regions in Sweden with the objective to accelerate the number of tender awards. But we have to be honest, the current circumstances have of course an impact on the market penetration. There is strong hope, as of Q2 2021, the number of face-to-face activities will increase which will have a positive impact on the ChloraSolv uptake.

2020 was also the year when RLS' second clinical trial, ChloraSolv01, was finalized. RLS is very pleased with the outcome and the first data were communicated at EWMA in November. The publication is under review and the aim is to publish the article in one high ranked journal early 2021. It is an important milestone and provides more, very interesting, data related to ChloraSolv.

In parallel, RLS has worked in close cooperation with researchers from Lund University. Additional pre-clinical data have been developed and will be published early 2021. This pre-clinical data and the data from ChloraSolv01, support significant changes which will improve the ChloraSolv claims. RLS has submitted the changes to the notified body, Eurofins. The objective is to broaden the indication to leg ulcers, improved biofilm claims as well as strengthen the debridement claims. Also, the shelf life has been extended from 12 to 24 months.

2020 is the year we submitted the approval dossier for Australia and Kuwait. There are no open questions from the authorities and RLS is awaiting the final approval, but the process has been delayed due to the pandemic. The authorities prioritize products and technology supporting the fight against covid-19. In the meantime, RLS together with local distributors, prepare for the launch. Key opinion leaders are approached and as soon as the product is approved the launch will start. Australia is a high-end market with strong focus

on innovation. The stakeholders that are approached are ready to learn more about ChloraSolv as soon as the product is approved. The prevalence of patients with chronic wounds are high in the Middle East and is increasing rapidly every year. It is exciting that RLS is ready to launch ChloraSolv in two new regions hopefully early 2021.

The communication with FDA in USA is ongoing. RLS together with external consultants, are in the process to compile the documentation for a pre-IND meeting. The objective is to conduct the meeting during Q1 2021. The waiting line and respond time are extended these days due to the covid-19 situation.

Please spend some time and take part of the two new videos published on the website. There you will “meet” Annika Nordström, Key Account Manager, RLS Global, who makes an introduction to ChloraSolv. Hilde Ingebretsen, wound nurse at Danderyd hospital, is educating about the importance to conduct professional debridement as well as sharing patient cases with ChloraSolv. [Watch the videos here.](#)

I am very proud of the RLS team and the capacity to mitigate the business during such a challenging year as 2020. We all are looking forward to continuing the journey 2021, with more customer acceptance, launches in new regions and countries, many steps forward for the US market, further driving the long term business model for RLS and increase the focus on new indications.

I and the team wish you all a Merry Christmas and a Happy New Year!

//Karin

