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Response to combination therapy with a novel Hansenula-derived Pegylated-Interferon alpha-2-a and Ribavirin in Naïve Egyptian Patients with Chronic Hepatitis C , Genotype 4

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Introduction:

Egypt has the highest HCV prevalence in the world, mostly genotype 4, There are 2 PEG interferons (12-kDa linear & 40-kDa branched), both are derived from the expression system E.coli. A Hansenula-derived PEG-Interferon (Reiferon Retard[®]) is available in the Egyptian market since three years. As stated by the manufacturer, the yeast expression system Hansenula polymorpha stands for a stable, robust and safe expression system, which has reached one of the highest productivities for a recombinant protein ever described. (Muller, 2009)

Aim:

To assess the efficacy, safety and compliance of alpha 2 a 20-kDa linear PEG interferon (Reiferon Retard[®], Minapharm, Egypt) derived from Hansenula Polymorpha expression system combined with Ribavirin for the treatment of chronic HCV-genotype 4 Egyptian patients

Patients and Methods:

Two hundred chronic HCV- genotype 4 naive patients were enrolled. Patients received a fixed weekly dose of 160 µg of the PEG interferon in combination with Ribavirin in a dose ranging from 11-13mg/kg and were followed up by PCR after 3, 6, 12 months (end of treatment response, ETR), 18 months (Sustained Virological Response, SVR). Encountered side effects, and concomitant use of cytokines were reported.

Results:

Eleven patients did not show-up at follow-up times. At 3 months, the overall response was 73 % (138/189). At 6 months the overall response was 67.8% (130/189 patients). At 12 months the overall ETR rate was 60.8% (115/189) and SVR at 18 months revealed an overall response rate of 53.4% (101/189) viral clearance. No discontinuation of therapy due to any adverse events especially haematological ones. Concomitant use of cytokines was only reported in 2% of cases due to neutropenia.

Conclusion:

We document the efficacy and safety of a novel Hansenula-derived Pegylated interferon alpha 2- a 160 µg & ribavirin in HCV-genotype 4 Egyptian naive patients.



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