NEXAVIR

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Dear Concierge Members:

I will review below the scientific data available for Nexavir for both its FDA approved uses in inflammatory skin disorders and its non-FDA approved uses as an anti-viral and its clinical effects in CFS cases.

At the center of Nexavir's scientifically studied benefits to CFS cases are two articles,

1) Steinbach et al, Clinical Infectious Diseases 1994; IS (Suppl 1):S114

2) Steinbach T., Hermann W – Internal publication from DNA Sciences Inc, Houston, TX, 1992 and presumably used in a patent application.

I have reviewed both articles with perhaps the DNA Sciences paper the most extensive and adds laboratory proof of a Kutapressin (aka Nexavir) benefit as well as a better therapeutic design which gave an 85% response rate described as good to excellent and a 13% modest response rate and a 2% nonresponse rate including a roughly 1% negative response (5 cases out of 600 treated).

The improved response was primarily due to at least a 6-month long therapy of at least 2 ml per day injected by IM. SQ is allowed but a slightly greater degree of initial problems was seen, probably due to the immune activation present in CFS and which is more easily induced further by SQ injection compared to IM.

Background of Kutapressin (aka Nexavir), an injectable liver extract originally developed by Schwartz Pharma, Mequon, WI and whose rights were sold to Nexco-Pharma, Houston, TX in the early 1990's with a name change to Nexavir.

1) The injectable extract was originally developed in the late 1940's

2) Found effective in the 1950's in treating inflammatory skin diseases including acne and poison ivy due to its vasoactive, bradykinin inhibitory properties.

3) Found effective in the 1960's as a possible anti-viral due to its effectiveness in treating herpes zoster (Shingles)

4) Found to be effective in inhibiting HHV-6 in vitro by Dharam Ablashi at NCI, a co-discoverer of HHV-6

5) Originally reported to be effective in treating 270 CFS cases by Drs Steinbach and Hermann in 1990 with 75% reporting recovery or near recovery

6) A re-designed study in 1992 with laboratory evidence of improvement in an additional 130 CFS patients using an immune response test (SLIF) showing a

reversal of immune response inhibition otherwise characteristic of CFS. The SLIF test is a flow cytometry adaptation of a long used immune test used in transplant patients to make sure they are immune suppressed.

The key difference in the 1992 study besides the SLIF assay was that the protocol was more aggressive using up to 2 ml of IM injections for 6 months and then a slow taper to 2 ml IM twice a week for a month and then 2 ml once a week for a month and then off. If there is a relapse, then going back to 2 ml daily for 10 days before resuming the original taper.

The results of the 1992 study of 130 CFS cases were that 85% had a good to excellent response with return or near return to normal daily activities and 13% additional CFS cases had a moderate response but unable to return to normal daily activity and 2% failed to respond with perhaps half of those or 1% with a negative response.

Nexavir is a notably safe drug used for over 70 years. It has very useful anti-inflammatory, anti-viral and immune-regulating benefits. On the downside, it is relatively costly at roughly $337.5 per month per ml used once a day with a cost of $675/month minimum for 2 ml daily and this is wholesale cost which Dixie can obtain for my patients directly from Nexco-Pharma. I would recommend SQ self-injection into the lower abdomen using a pinched skin routine of self-injection with two back-to-back 1 ml injections daily using a 31 gauge, 1 ml insulin syringe. The first injection should be 0.1 ml SQ to make sure you tolerate Nexavir. Nexavir is also available as a skin paste (Nexco Cream) at about $475 per month but for some it may be less effective though is dose equivalent to $675 per month of the injectable.

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