RMV
TRADEMARKS, LLC

EES - Essential Eyebrow Solution® Presentation

Company Overview

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EES™ Discussion

RMV Overview

- RMV Trademarks, LLC ("RMV") is focused on developing a portfolio of eyebrow preservation and enhancing products that address thinning eyebrows due to a number of causes including: cancer treatment, alopecia areata (non-cancer related), thyroid disorders, excessive tweezing or waxing, and aging. RMV will expand its cosmetic line to include various products designed to complement natural beauty. The products will be gentle, yet effective, suitable for both male and female, and mild enough for use by chemotherapy and post-chemotherapy patients.

- This presentation will focus on the launch of the first product on RMV's platform, EES-Essential Eyebrow Solution®, which nourishes and protects eyebrow hair, especially for cancer patients facing hair loss in connection with chemotherapy treatment.

- Until now, no method has been available for the prevention of chemotherapy-induced eyebrow hair loss. EES-Essential Eyebrow Solution® is a safe and effective formulation that offers patients a substantial increase in self-esteem and quality of life, thereby significantly decreasing the physical and psychological ramifications of chemotherapy.

- EES™ is a topical solution comprised of an herbal extract known as black cohosh, formulated with other ingredients that are commonly used in cosmetic products. Black cohosh is native to North America and has been used for many medicinal purposes.

RMV Overview

- RMV submitted a Pre-IND application to the FDA and has received guidance from the FDA indicating EES™ could be further developed as a botanical drug according to the Guidance for Industry: Botanical Drug Products guidelines.

- A comprehensive regulatory analysis of the EES™ product was conducted by Regulatory Affairs Associates, Inc., and the results led RMV to determine that EES™ should come to market at this time as a cosmetic, with limited claims.

- A strategic marketing analysis of the EES™ product was conducted by Morpace, Inc. in Farmington Hills, Michigan, using in-depth qualitative and quantitative interviews. The vast majority of cancer patients interviewed (85%) expressed strong interest in using the EES™ product.

- EES™ is protected by multiple issued United States patents, and RMV is pursuing patent protection in Europe and Canada.

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- Associate Clinical Professor, Department of Medicine, Wayne State University School of Medicine
- Senior Staff Physician, Hematology/Oncology, Josephine Ford Cancer Institute
- Medical Director, Clinical Trials Office, Josephine Ford Cancer Institute

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- Professor, Department of Dermatology, Case Western Reserve University and University Hospitals Case Medical Center
- Director, Center for Medical Mycology, Case Western Reserve University and University Hospitals Case Medical Center
- Tenured professor, Case Western University School of Medicine

Afif Ghannoum, JD

- Vice President, ARMS Pharmaceutical, Cleveland, OH

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- The American Cancer Society estimates that approximately 1,658,370 cancer cases were diagnosed in the United States in 2015.
- Each year, approximately 650,000 cancer patients receive chemotherapy in outpatient oncology clinics in the United States. It is estimated that 65% of the patients who undergo chemotherapy treatment experience overall hair loss.
- More than 80% of chemotherapy patients consider hair loss to be the worst aspect of their chemotherapy experience.
- It has been reported that 8% of female cancer patients say they would decline treatment for fear of hair loss.
- For men, hair loss during chemotherapy negatively affects their self-perception of virility and masculinity.
- While scalp hair loss can be disguised, the loss of eyebrows can be difficult to hide and is often perceived by patients as an unwelcome, very visible sign of their illness.
- Eyebrows are one of the most important features of the face. In addition to protecting the eyes from sweat, dust and debris, eyebrows create a frame for our face, are an important part of our attractiveness, and are vital to our nonverbal communication.

Consumer Interest

- Eyebrow hair loss results in cosmetic changes that cause substantial emotional distress for many cancer patients, both male and female.

- Few satisfactory options exist to remedy the loss of eyebrows in connection with chemotherapy treatment. Frequently employed efforts include:
  - stencils to pencil in an eyebrow
  - tattoos
  - artificial hairs shaped like an eyebrow, which are adhered to the skin

- Artificial replacements offer no range of emotion or facial expression and do little to improve the psychological sequelae of eyebrow loss.

- In summary, the ramifications of eyebrow hair loss impose a significant psychological burden on chemotherapy patients. This is remedied by a novel prophylactic approach such as EES™ to prevent eyebrow hair loss.

- The sizeable number of cancer diagnoses in the U.S. lends a compelling argument for a safe and effective product which protects against eyebrow hair loss associated with chemotherapy. EES™ is the first and only product to remedy this problem.

Photos demonstrating dramatic change in appearance when the eyebrows are lost

Photos demonstrating dramatic change in appearance when the eyebrows are lost

Market Research Confirms EES™ Market Potential

RMV conducted a strategic marketing assessment of EES™, using in-depth qualitative and quantitative interviews of 95 cancer patients who had recently undergone chemotherapy or were currently in treatment. Demographic and segmentations include:

	East Coast (NY/NJ/PA)	West Coast (CA)	Total
Female	24	34	58
Male	17	20	37
Total	41	54	95

Results demonstrated that:

- "Wanting to look natural/normal" and "better self-esteem" are two primary consumer needs. Retaining eyebrows during chemotherapy helps with both of these needs.
- Approximately 53% of chemotherapy patients are very concerned about losing their eyebrow hair.
- A total of 85% of participants showed interest in trying EES™. The participants were patients who learned they were likely to experience full body hair loss in connection with chemotherapy treatment and who were given an initial description of the product.
- Consumers will recommend this product. There is potential for strong word-of-mouth promotion.
- Patients would feel most compelled to try EES™ if their doctor, pharmacist, or other chemotherapy patients recommended it.
- Almost four in ten chemotherapy patients said they had researched methods of preventing or hiding hair loss with hopes of achieving specific benefits like regrowth of hair, or a natural or normal appearance.
- Results indicated that there is a sizeable U.S. market opportunity for this product.

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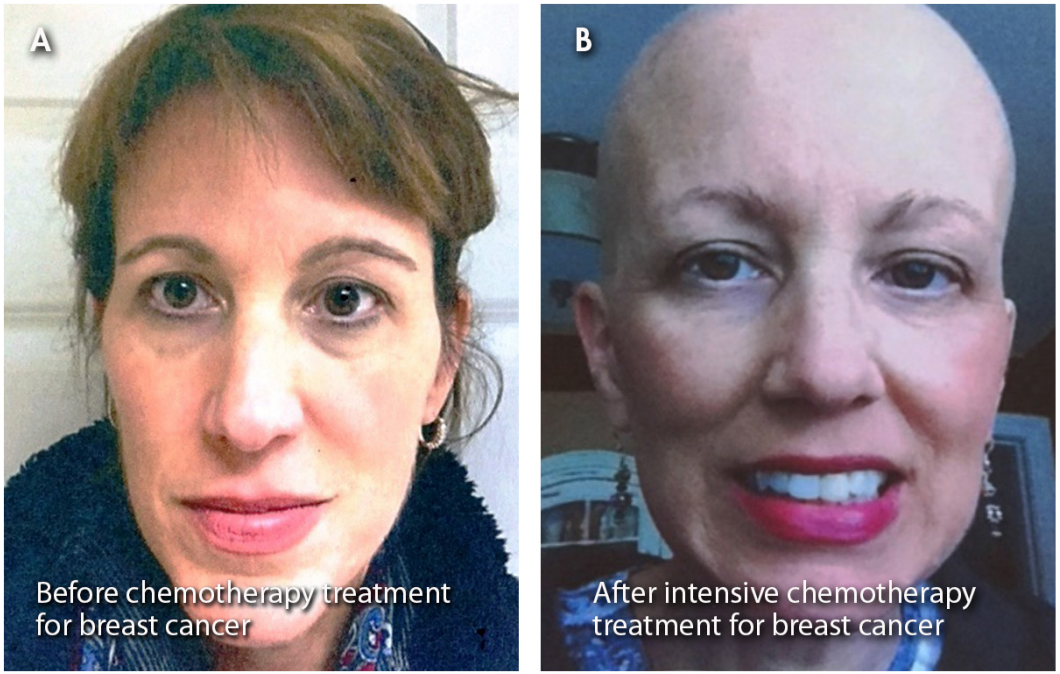
Mechanism of Hair Loss in Cancer Patients

- Cancer cells exhibit rapid cell division and proliferation.
- Chemotherapy treatment targets all rapidly dividing cells by damaging cell structures or metabolism.
- Chemotherapeutic agents impair mitotic and metabolic processes of actively growing hair follicles. This disruption of the hair growth cycle causes hair loss.
- In addition, chemotherapy causes impairment through a weakening of the partially keratinized, proximal portion of the hair shaft, resulting in thinning, fragility, and breaking of the hair shaft.

Chemotherapy and Hair loss

- There are four major classes of chemotherapeutic agents that commonly induce hair loss.
- The extent of hair loss differs across each chemotherapy class.
- The chemotherapy classes are:
  - Antimicrotubule agents (e.g., paclitaxel),
  - Topoisomerase inhibitors (e.g., doxorubicin),
  - Alkylators (e.g., cyclophosphamide),
  - Antimetabolites (e.g., 5-fluorouracil plus leucovorin)
- Drugs with high potential for hair loss include: adriamycin, cyclophosphamide, daunorubicin, docetaxel, epirubicin, etoposide, ifosphamide, irinotecan, paclitaxel, topotecan, vindesine, and vinorelbine.
- Paclitaxel typically induces complete hair loss, including both the scalp and eyebrows.
- Adriamycin induces complete hair loss on the scalp, and very often causes eyebrow hair loss.
- Drugs such a methotrexate, cytoxan, carboplatin, and 5-fluorouracil can cause hair loss in some patients, but not others.



Chemotherapy Regimen consisted of: Perjeta, Taxotere, Carboplatin & Herceptin (every 3 weeks X 6 cycles), followed by Herceptin every 3 weeks for one year.

"Thank you for the opportunity to use this product during my chemotherapy. The ability to maintain my natural eyebrows during my treatment made a significant psychological difference when dealing with my other losses. With a wig, eyeliner and the preservation of my own eyebrows, others frequently commented on their amazement that I had not lost my hair…when indeed I had. The loss of eyelashes and the hair on one's head are far easier to conceal than the loss of one's eyebrows. I felt very fortunate to have had access to this product!" - Lynn

EES™: A Topical Eyebrow Preservation Drug

- EES™ is a botanical formulation with the proposed indication of preserving eyebrow hair during chemotherapy treatment.
- EES™ is a topical solution comprised of an herbal extract (black cohosh), formulated with other ingredients that are commonly used in cosmetic products.
- The active ingredient in EES™, black cohosh (Cimicifuga racemosa), has been used for many medicinal purposes. It is a perennial herb native to North America with a large, creeping rhizome.
- EES™ is applied directly to the eyebrow as shown in Figure 1.

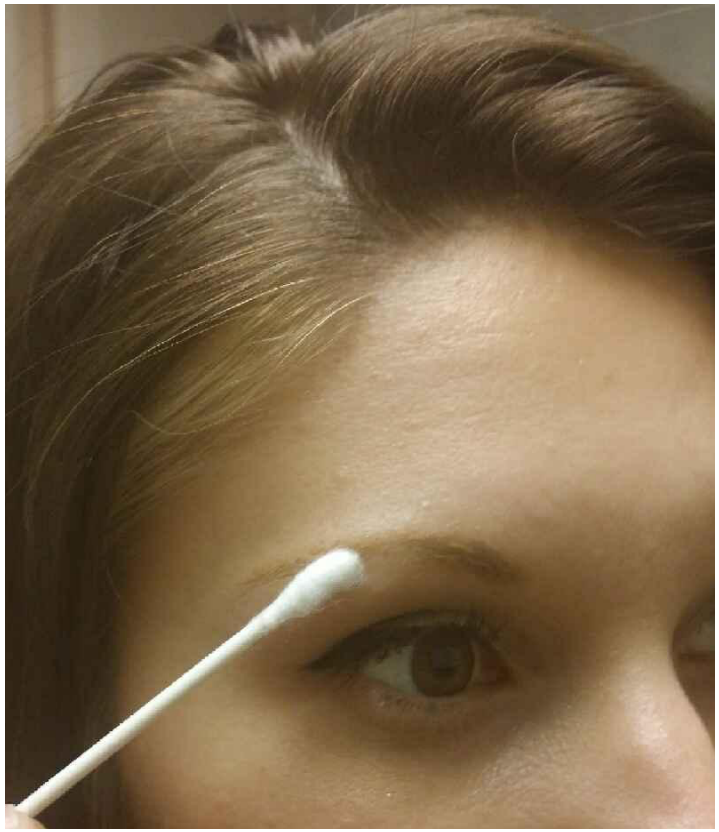


Figure 1 Application of EES™

EES™ Mechanism of Action

- The mechanism of action of EES™ is unclear.
- The active ingredient, black cohosh, is a resinous substance known as cimicifugin or macrotin.
- Studies have shown that black cohosh extracts contain several compounds that may contribute to its activity, including: cycloartane, triterpene glycosides (such as acetin and 26-deoxyactein), henylpropanoid esters, and phenolic compounds (such as caffeic acid derivatives).
- RMV believes that the retention of eyebrow hair may be the result of the impact of EES™ on the hair follicle through a hibernation effect, which halts or delays hair growth during chemotherapy, thereby preventing hair loss.
- Eyebrow hair differs from scalp hair in several respects:

  – For eyebrow hair, the growth cycle is very short, typically about 4 months. Scalp hair, on the other hand, has a growth cycle that takes 3-4 years to complete.

  – Eyebrow hair emerges from the follicle at a very acute angle, which produces growth that is essentially parallel to the skin surface. By contrast, the angle between scalp hair and the skin can be 45 degrees or more.

  – Eyebrow hairs grow on a single strand, whereas several hairs arise from a single follicle on the scalp.

EES™ Science

- The EES™ formulation was developed when it was found that extracts from black cohosh were a common ingredient in certain compositions of hair loss remedies.

- Unlike those remedies directed at scalp hair, EES™ has been specifically formulated for application on eyebrow hair.

- EES™ formulation was compounded by a research laboratory under Good Manufacturing Practices.

- Since there is no approved, standardized utilization or application of black cohosh for eyebrow hair loss, the safety and efficacy of the EES™ formulation was established through a series of non-clinical and clinical studies conducted by RMV. The results were highly favorable.

EES Safety Studies

- Historical use and literature suggest both the active ingredient and excipients in EES™ are safe for topical use.

- To further confirm safety, the formulation has been extensively tested for its stability and safety by RMV, using three independent laboratories.

- RMV conducted these studies to assess the topical safety of EES™:
  - Chorioallantoic membrane vascular assay (CAMVA-14 Day)
  - Bovine corneal opacity and permeability test (BCOP)
  - Eyebrow Preservation during Chemotherapy Pilot Clinical Trial
  - Repeat insult patch test (semi-occlusive patch) skin irritation/ sensitization evaluation (RIPT)

CAMVA Study

- RMV conducted the CAMVA study using an alternative to the Draize methodology to determine the potential for ocular irritation.
- Based on the results of a preliminary screen, the chorioallantoic membrane (CAM) of forty white leghorn eggs, incubated for 14 days, was dosed with 40 μl of EES.
- A total of four concentrations were used, one per group.
- The dosed eggs were then incubated for another 30 ± 5 minutes after which the CAM was observed for signs of vascular hemorrhage, capillary injection, or ghost vessels. The RC50 was determined.

The positive responses to the four dilutions in distilled water were as follows:

Concentration (%)	# of Eggs	# of Positive responses
25	10	0/10
50	10	5/10
75	10	6/10
100	10	10/10

The positive responses were characterized by capillary injection and hemorrhage. In conclusion, the RC50 and 95% Confidence Limits were 56 (38-82)%. Based on the results of this study, it was concluded that EES™ is considered a non-irritant.

BCOP Study

- RMV conducted the BCOP study using an alternative to the Draize methodology to determine the potential for ocular irritation.
- Five corneas were dosed with 0.75 ml of EES™.
- Opacity measurements and sodium fluorescein permeability were determined.
- The corrected mean opacity score was 1.3.
- The corrected mean optical density (permeability) score was -0.005.
- In conclusion, the in vitro score was calculated as 1.23, and therefore EES™ is considered a non-irritant.

RIPT Study

- RMV conducted a Repeat Insult Patch Test to ensure that EES™ does not cause skin sensitization or irritation.
- The RIPT was conducted under good clinical practices with an attending dermatologist and institutional review board (IRB) approval.
- The RIPT was conducted on 50 healthy male and female subjects, with an age range of 19-68 years.
- A 0.2 ml or 0.2g of the test material was dispensed onto a semi-occlusive, hypoallergenic patch and applied to various areas of the body.
- After 24 hours the patch was removed by the patient at home.
- This procedure was repeated for nine 24-hour exposures over three weeks.
- Adverse reactions, if any, were confirmed and measured.
- A review of the data by the consulting dermatologist confirmed the following:
  - No adverse events of any kind were observed.
  - As a result, EES™ can be considered a non-primary irritant and non-primary sensitizer to the skin.

Open-Label, Dose-Ranging Clinical Study

- RMV conducted a preliminary clinical study of chemotherapy treatment subjects in order to demonstrate the safety and efficacy of EES™ for protection against eyebrow hair loss during chemotherapy.

- The study was an open-label, dose-ranging, two-phase study of 150 consenting cancer subjects undergoing chemotherapy treatment, using EES™ at various concentration levels. The enrolled subjects were undergoing treatment with various chemotherapy regimens that are known to cause full body hair loss.

- The study results demonstrated that 91% (n=40) of the subjects utilizing the optimum dose of 5% (pH 5–6) of EES™ retained 50–100% of their eyebrow hair, despite experiencing full body hair loss elsewhere.

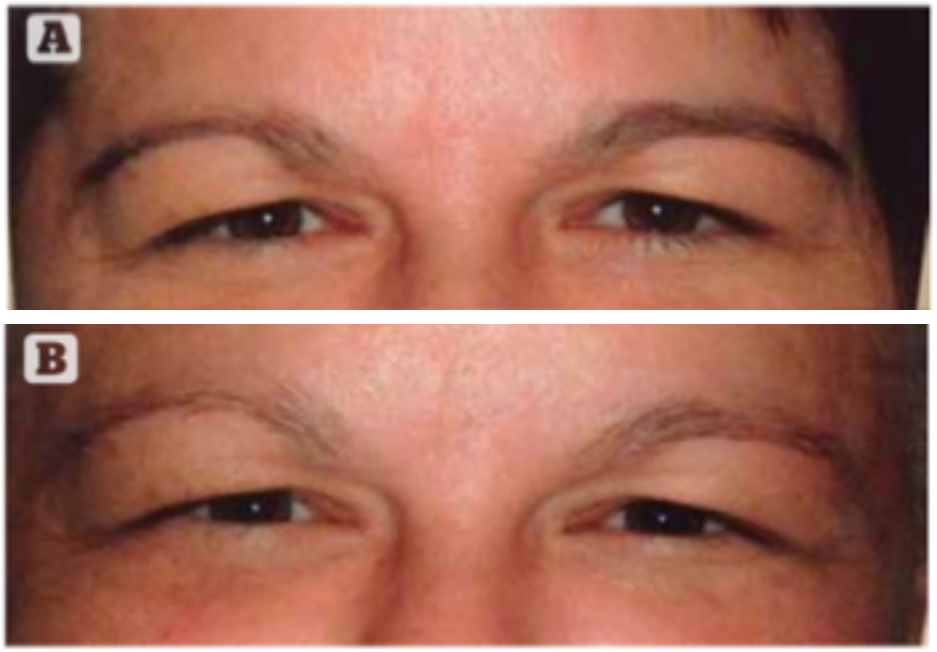
- The study data showed that 5% (pH 5–6) EES™ is a safe and effective topical application for protection against eyebrow hair loss in cancer patients undergoing chemotherapy.

Clinical Trial Before-and-After Photographs

- The following are two sets of before-and-after photos showing the retention of eyebrow hair in patients using the 5% (pH 5–6) EES™ formulation.
- These subject-specific results are representative of the majority of the subjects assigned to the same dosage group.

(A) Subject #58 before applying the 5% (pH 5-6) EES™ formulation, prior to undergoing 12 weeks of chemotherapy consisting of Taxotere and Cytoxan for breast cancer

(B) Subject #58 during period of full body hair loss with the exception of the eyebrows, which were retained after chemotherapy



Clinical Trial Before-and-After Photographs

(A) Subject #73 before applying the 5% (pH 5-6) EES™ formulation, prior to undergoing 18 weeks of chemotherapy, consisting of Taxotere and Cytoxan for breast cancer

(B) Subject #73 after applying the 5% (pH 5-6) EES™ formulation, while undergoing 18 weeks of chemotherapy, consisting of Taxotere and Cytoxan for breast cancer, retaining almost 100% of her eyebrow hair, despite full body hair loss elsewhere

EES™ Safety Conclusions

- Trials conducted by RMV demonstrate that EES™:
    - Does not cause eye irritation
    - Is not a skin sensitizer/irritant
    - Does not pose safety concerns when applied topically

Collectively, the history of use, literature, and conducted studies provide substantial evidence that EES™ is safe.

EES™ Allows for Additional Potential Eyebrow Preservation Drug Indications

In addition to eyebrow retention during chemotherapy, there are a number of other potential applications for EES™, including eyebrow hair loss due to:

- Alopecia areata (non-cancer related)
- Thyroid disorders
- Aging
- Excessive tweezing, waxing, or threading

Robust Patent Portfolio

EES™ is supported by a robust patent portfolio

- ESS™ has been granted two patents by the United States Patent and Trademark Office:
  - Composition patent
    - US Patent No. US8394428 B1
    - Publication date: March 12, 2013
  - Method of Use patent
    - US Patent No. US8309142 B1
    - Publication date: November 13, 2012

- RMV is pursuing additional patent protection with applications in Europe and Canada.

- The composition is broad in two practical aspects:
  - It requires only three ingredients (black cohosh extract, nonionic surfactant, and hydroxylated solvent).
  - The nonionic surfactant is not limited to any particular type.

- Per the method claims, the composition can be applied in any delivery system.

Peer-Reviewed Publication of EES™ Open Clinical Trial Data

- EES™ open trial clinical data has been published in a peer-reviewed journal, *PRIME International Journal of Aesthetic & Anti-Ageing Medicine*

- The article is entitled "Preserving Eyebrow Hair during Chemotherapy Treatment."

- The article was written in collaboration with Josephine Ford Cancer Institute/ Henry Ford Health System, located in Detroit, Michigan.

- Authors of the article are:
  - Ding Wang, MD, PhD - Senior Staff Physician of Hematology/Oncology and Director of the Clinical Trials Office, Josephine Ford Cancer Institute
  - Carolie Horvath, RN, BSN, CCRC - Quality Assurance Specialist at the Clinical Trials Office, Josephine Ford Cancer Institute
  - Susan D. Lewis, PhD - Research Specialist, Regulatory Affairs Associates, Inc.

- The article was published in the North American and European edition of *PRIME* (May/June 2015).

PRESERVING EYEBROW HAIR DURING CHEMOTHERAPY TREATMENT

Ding Wang, Carolie Horvath and **Susan D. Lewis** discuss the results of their open-label, dose-ranging study on the use of Essential Eyebrow Solution for protection against eyebrow loss

Regulatory

- Through the Pre-IND process (PIND # 125068), RMV solicited FDA's input regarding the steps required to complete the development of EES™ as a botanical drug with the indication of preserving eyebrow hair during chemotherapy treatment.

- After receiving FDA's written response to the Pre-IND submission, RMV has a detailed guiding document from FDA regarding the remaining necessary steps and activities required to develop EES™ as a new botanical drug.

- RMV's Pre-IND submission, and the FDA's corresponding response is available upon request.

EES™ Development Summary

- RMV has received FDA guidance on next activities in the drug approval pathway.
- At this time, RMV has elected to bring EES™ to commercialization as a cosmetic product in the interest of those individuals who would benefit from its use.
- The Composition and Method of Use are patented for EES™.
- Literature, safety data, and clinical trial results suggest low risk to commercialization of EES™.
- EES™ has demonstrated effectiveness against eyebrow hair loss during chemotherapy.
- The EES™ platform allows for other potential eyebrow preservation drug indications.

Strategic Overview

RMV is committed to providing pure, safe, and soothing botanical products for everyday beauty and good health. The products developed by RMV will also improve the quality of life for chemotherapy patients worldwide by helping them retain a vibrant, healthy appearance while protecting their eyebrows, fragile skin, and hair during and after treatment. Studies have shown appearance directly affects the self-esteem and psychological well-being of cancer patients and RMV hopes to do its part to benefit these important, under-served individuals. Through their Share Campaign, RMV will be making donations to various cancer-related charities.

For Further Information

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